

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA  
PITTSBURGH

In re: Viatris Inc. Securities Litigation

2:23-CV-00812-MJH

OPINION

Plaintiff Shareholders bring the within putative class action against Defendants, Viatris, Inc. and two of its corporate officers and directors, Michael Goettler and Rajiv Malik, for violations of Section 10(b) of the Securities Exchange Act (15 U.S.C. § 78j(b)) (Count I), and against Messrs. Goettler and Malik for violations of Section 20(a) of the Securities Exchange Act (15 U.S.C. § 78t(a)) (Count II). (ECF No. 51). Defendants now move for dismissal pursuant to Fed. R. Civ. 12(b)(6). The matter is now ripe for disposition.

Upon consideration of the Class Action Amended Complaint (ECF No. 51), Defendants’ Motion to Dismiss (ECF No. 54), the respective briefs (ECF Nos. 55, 58, and 62), affidavits and declarations (ECF Nos. 56, 59, and 63), and for the following reasons, Defendants’ Motion to Dismiss will be granted.

I. Background

Viатris is a global healthcare company. (ECF No. 51 at ¶ 20). Viатris was formed on November 16, 2020, through the combination of Mylan N.V. (“Mylan”) and Pfizer Inc.’s off-patent brands and generics division, Upjohn Inc. (“Upjohn”). *Id.* at ¶¶ 1, 20, 24. Michael Goettler served as Viатris’ Chief Executive Officer and as a Viатris Director from the Company’s inception in November 2020 until April 2023. *Id.* at ¶ 21. He previously served as Group

President of Pfizer’s Upjohn division from July 2018 until the November 2020 merger between Upjohn and Mylan to form Viatris. *Id.* at ¶ 21. Rajiv Malik has served as Viatris’ President and as a Viatris Director since November 2020. *Id.* at ¶ 22. He previously served as President of Mylan from January 2012 until the formation of Viatris. *Id.* at ¶ 22.

Following Viatris’ formation in November 2020, the Company repeatedly made clear that combining Mylan and Upjohn would involve “significant” reshaping of the blended business, which had products spanning brands, complex generics, and biosimilars in four geographic segments. (ECF No. 56-2). The day the merger closed, Viatris announced that it was “embarking on a significant global restructuring program.” *Id.* About one month later, on December 11, 2020, Viatris announced that it was “continu[ing] to develop the details of the global restructuring program” in furtherance of its “business transformation efforts.” (ECF No. 56-3). On February 22, 2021, the Company announced its financial guidance for its first full year of operation—projecting 2021 revenue between \$17.2 and \$17.8 billion and adjusted EBITDA (Earnings Before Interest, Taxes, and Depreciation) between \$6.0 and \$6.4 billion, with a midpoint of \$6.2 billion. (ECF No. 51 at ¶ 47). Viatris also continued to emphasize its “multiyear global restructuring initiative.” (ECF No. 56-4 at 5-6).

On March 1, 2021, at Viatris’ inaugural Investor Day, in addition to discussing the business and projecting that 2021 would be “a trough year” in revenue, adjusted EBITDA, and cash flow, the Company disclosed that it “expect[ed] to begin [its] strategic planning exercise over the next coming months,” which would provide “[m]ore visibility into [the Company’s] 3 years outlook.” *Id.* at ¶¶ 53, 70, 72, 139, 141; ECF No. 56-5 at 36. Mr. Goettler twice stated, including in his closing remarks, that “[w]e’re on a multiyear journey to transform this company.” *Id.* at 9, 52. The same day, Viatris filed its first annual report on Form 10-K, which

disclosed: [W]e . . . continue to consider and evaluate various strategic transactions and business arrangements on an ongoing basis, including . . . divestitures [and] product rationalization . . . . These transactions and arrangements may be material both from a strategic and financial perspective. . . . Furthermore, although our expectation is to engage in divestitures and product rationalizations only if they advance or otherwise support our overall strategy, any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets or products. (ECF No. 56-1 at 21-22). Following Investor Day and throughout 2021, Defendants repeatedly disclosed that Viatris was engaging in a strategic review to transform the Company, stating specifically that the strategic review was a “rigorous bottom-up strategic planning effort” (ECF No. 51 at ¶¶ 92, 173). This included examining “all the strategic levers at [Viatris’s] disposal” including the “potential divestitures of products and businesses” *Id.*; (ECF No. 56-6 at 62; Ex. ECF No. 56-7 at 75; Ex. 56-8 at 75). Viatris also disclosed that the projection of \$6.2 billion adjusted EBITDA for 2021 “was meant as ‘a floor in an interim period while we’re looking on our long-term outlook’ and ‘strategic plan,’ at which point [the Company] will ‘give guidance for 2022 and years beyond.’” ¶ 96 (quoting Ex. 9 at 6).

After reporting its financial results for the first three quarters of 2021, on August 9, 2021, based on “the underlying strength of the business,” Viatris raised its financial guidance for 2021, upwardly adjusting estimated total revenues to \$17.5 to \$17.9 billion and adjusted EBITDA to \$6.15 to \$6.45 billion, with a midpoint of \$6.3 billion. (ECF No. 56-11 at 5). On November 8, 2021, Viatris again raised its financial guidance for 2021, upwardly adjusting estimated total revenues to \$17.7 to \$17.9 billion and adjusted EBITDA to \$6.3 to \$6.5 billion, with a midpoint of \$6.4 billion. (ECF No. 56-12 at 6). At year-end 2021, Viatris reported results were near the

high end of those ranges: revenue of \$17.886 billion and adjusted EBITDA of \$6.426 billion. (ECF No. 56-13 at 13, 17).

On February 28, 2022, at Viatris' 2022 Investor Event, the Company announced the "completion of [its] comprehensive strategic review[.]" (ECF No. 56-13 at 2). At that time, Viatris stated that "[a]s you know, in December 2020, we already announced a significant global restructuring plan and executed against this plan. . . . [T]hrough 2021, we conducted a thorough strategic review of our entire business." (ECF No. 56-14 at 4-5). Viatris explained that it had "identified certain assets as a part of an extensive strategic review. . . [that] have a potential to unlock the trapped value and are potentially noncore to the future direction of the company." (ECF No. 56-14 at 5-6; ECF No. 51 at ¶¶ 108, 119). Viatris further announced, that as the "first bold step in its long-term strategy," it had entered into a strategic venture with Biocon, in which Viatris would contribute to Biocon its biosimilars portfolio and related commercial and operational capabilities in exchange for Viatris receiving a stake of at least 12.9 percent of the equity in Biocon, plus payment of up to \$3.335 billion (the "Biocon Transaction"). (ECF No. 56-13 at 2). Biocon had a longstanding strategic partnership with Viatris, dating back to Mylan pre-merger, when Mylan and Biocon had commercialized several biosimilars. (ECF No. 51 at ¶¶ 35-36). The parties executed the Transaction Agreement on February 27, 2022, one day before it was publicly announced. (ECF No. 56-15). Following the transaction, Viatris was to continue to pursue its "broad-based portfolio," including "generics, complex generics, [and] off-patent brands," and Viatris was to use the funds received pursuant to the Biocon Transaction Agreement to make additional investments to further expand the scope of Viatris' portfolio. Viatris planned to pursue innovative and higher-margin products, focusing on the

ophthalmology, gastrointestinal, and dermatology therapeutic areas. (ECF No. 56-14 at 7, 9-10, 15, 21).

In addition, on February 28, 2022, Viatis announced its fiscal year 2022 guidance. (ECF No. 51 at ¶ 116). Viatis forecasted 2022 revenue between \$17.0 and \$17.5 billion, adjusted EBITDA between \$5.8 and \$6.2 billion with a midpoint of \$6.0 billion, and free cash flow between \$2.5 and \$2.9 billion. *Id.* Viatis' CFO explained that the lower-than-expected EBITDA guidance was driven by two industrywide factors: (1) foreign exchange impact from the strengthening of the dollar in the second half of 2021 and beginning of 2022; and (2) inflation impact upon input costs. *Id.* at ¶ 128; ECF No. 56-14 at 17.

Plaintiffs' Amended Complaint alleges that, during the alleged Class Period of March 1, 2021 to February 25, 2022, Defendants violated Securities Exchange Act Section 10(a) (15 U.S.C. § 78j(b)) and Section 20(a) (15 U.S.C. § 78t(a)), by making material misstatements or omissions in their SEC filings, quarterly earnings calls, and investor conferences concerning Viatis' (1) "strategy to leverage its broad and diverse portfolio spanning all categories of pharmaceutical products;" (2) "commitment to biosimilars as the Company's key growth driver;" and (3) financial outlook, "specifically its growth from its 2021 'trough year' and 'floor' of \$6.2 billion in adjusted EBITDA." (ECF No. 51 at ¶ 137; see also ¶¶ 138-200).

## II. Relevant Standards

In determining whether a complaint states a cause of action sufficient to survive dismissal under Fed. R. Civ. P. 12(b)(6), the Court must "accept all well-pleaded allegations as true and draw all reasonable inferences in favor of the plaintiff." *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp.*, 908 F.3d 872, 878 (3d Cir. 2018). "[T]hreadbare recitals of the elements of a cause of action, legal conclusions, and conclusory statements" are all disregarded. *Id.* at 878-

79 (quoting *James v. City of Wilkes-Barre*, 700 F.3d 675, 681 (3d Cir. 2012) ). The plaintiff’s right to relief must be more than speculative; it must rise to the level of plausibility. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A claim meets the “plausibility” standard only if the factual allegations permit the Court to “draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 678).

Claims under the Securities Exchange Act Section 10(a) and Rule 10b-5 must also meet the requirements of Fed. R. Civ. P. 9(b), which requires fraud allegations to “state with particularity the circumstances constituting fraud or mistake.” In addition, under the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u-4 thereof imposes heightened particularity requirements on the material misrepresentation and scienter elements for these claims. *City of Cambridge Ret. Sys.*, 908 F.3d at 879.

In consideration a motion to dismiss, “courts must consider the complaint in its entirety, as well as ... documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.” *Inst. Inv’rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007)). For a motion to dismiss in a securities fraud action, the Court may take judicial notice of matters of public record, such as SEC filings, and documents “integral to or explicitly relied upon in the complaint.” *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014).

### III. Discussion

Defendants argue that Plaintiffs have failed to plead that the alleged misstatements or omissions are actionable under the Private Securities Litigation Reform Act’s (PSLRA) Safe Harbor provisions, (15 U.S.C. § 78u–5(c)(1)). They also argue that the Amended Complaint

fails to plead facts to establish the elements necessary to support a Section 10(a) claim under the Securities Exchange Act, 15 U.S.C. § 78j(b). Specifically, Defendants contend that Viatrix' forward-looking and cautionary statements are protected by PSLRA Safe Harbor, and that the Amended Complaint fails to plead that any statements were made with "actual knowledge" of their falsity.

Plaintiffs contend they have adequately alleged that Defendants made materially misleading statements, that they actually knew their statements were misleading, and that the statements are not protected by the PSLRA's safe harbor.

#### A. Applicable Laws

##### 1. **Safe Harbor**

The PSLRA's Safe Harbor Provision provides that:

[A] person ... shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that—

(A) the forward-looking statement is—

- (i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or
- (ii) immaterial; or

(B) the plaintiff fails to prove that the forward-looking statement—

- (i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or
- (ii) if made by a business entity; was—
  - (I) made by or with the approval of an executive officer of that entity; and
  - (II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

15 U.S.C. § 78u–5(c)(1). *See Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 254 (3d Cir. 2009). Thus, the PSLRA’s Safe Harbor shields a defendant from liability where the challenged forward-looking statement is “identified as forward-looking,” and “accompanied by meaningful cautionary statements.” 15 U.S.C. § 78u–5(c)(1).

The term “forward-looking statement” is defined in the Safe Harbor statute, and it includes, “a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer,” as well as “any statement of the assumptions underlying or relating to any” forward-looking statement. 15 U.S.C. § 78u–5(i)(1)(B),(D).

As regards “meaningful cautionary statements,” “[they] must be extensive and specific.” *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 243 n.3 (3d Cir. 2004). Cautionary language must also be “directly related to the alleged misrepresentations, but it does not have to actually accompany the alleged misrepresentation.” *Id.* at 243 n. 3.

## **2. Sections 10(b) and 20(a)**

Section 10(b) prohibits the use of any “manipulative or deceptive device or contrivance” in contravention of SEC rules in connection with the purchase or sale of securities. 15 U.S.C. § 78j(b). Rule 10b-5 prohibits, in pertinent part, making an “untrue statement of a material fact or ... omit[ting] to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.” 17 C.F.R. § 240.10b-5(b). The private right of action under these provisions “creates liability for false or misleading statements or omissions of material fact that affect trading on the secondary market.” *Burlington*, 114 F.3d at 1417.



To state a claim for securities fraud under Section 10(b) and Rule 10b-5, a plaintiff must allege “(1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Martin v. GNC Holdings, Inc.*, 757 Fed. Appx. 151, 154 (3d Cir. 2018) (citing *Tellabs*, 551 U.S. at 322-23); *see also City of Cambridge Ret. Sys.*, 908 F.3d at 879. The PSLRA requires, with regard to the “material misrepresentation” element, that the complaint “‘specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading,’” and, as to any allegations made upon information and belief, “‘all facts on which that belief is formed.’” *City of Cambridge Ret. Sys.*, 908 F.3d at 879 (quoting 15 U.S.C. § 78u-4(b)(1)). As to scienter, the complaint must “‘state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.’” *Id.* (quoting 15 U.S.C. § 78u-4(b)(2)(A) ). To adequately plead this element, the inference of scienter, or “defendant's intention ‘to deceive, manipulate, or defraud,’” must be “more than merely plausible or reasonable--it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.” *Tellabs*, 551 U.S. at 314.

Section 20(a) provides that, persons who directly or indirectly control any person liable under the Exchange Act or rules promulgated under it, are jointly and severally liable with the controlled person for violations of the act, unless the controlling person “acted in good faith and did not directly or indirectly induce the acts constituting the violation or cause of action.” 15 U.S.C. § 78t(a). Put succinctly, “[l]iability under Section 20(a) ‘is derivative of an underlying violation of Section 10(b) by the controlled person.’” *Biondolillo v. Roche Holding AG*, 2018 WL 4562464, at \*18 (D.N.J. Sept. 24, 2018) (Thompson, J.) (quoting *Rahman v. Kid*

*Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013)). Accordingly, if no Section 10(b) violation has been adequately pleaded, the Section 20(a) claim also fails. *Id.*

## B. Analysis

In their Amended Complaint, Plaintiffs challenge 61 of Defendants’ statements in support of their Securities Fraud Claims. Defendants maintain that 49 of these statements are protected by the Safe Harbor provisions or are otherwise not actionable. As regards the Safe Harbor, Defendants have identified three categories of “forward-looking” statements: 1. “trough year” and “floor” projections for revenue, adjusted EBITDA, and cash flow; 2. future of the biosimilar business; and 3. product pipeline and portfolio statements. Defendants also maintain that the remaining 12 statements present representations of corporate optimism and opinion, which are not actionable.

### 1. Forward-Looking Statements

#### a. “Trough Year” and “Floor” Projections

Context	Statement Nos. 1, 2, 3, 12, 14, 15, 17, 19, 21, 28, 29, 30, 40, 42, 43, 52, 53, 60, and 61
March 1, 2021 Investor Day	<p><b>Statement No. 1</b></p> <p>I believe we accomplished the goal to give you enhanced visibility and understanding across P&amp;L and cash flow. <b>I want to reiterate that 2021 will be a trough year for revenue, adjusted EBITDA and free cash flow..... Again, just as a reminder, 2021 is a trough year for free cash flow.</b> I expect the cash flow to grow significantly over the next 2 years....Now based on that, we're not providing a long-term EBITDA guidance, <b>but one thing I can clearly tell you that our 2021 is the trough year for EBITDA, cash flow and revenue</b>, and that is what's there and particularly for free cash flow, we're expecting that to rapidly grow as some of the onetime payments go down.</p> <p><b>Statement No. 2</b></p> <p>And look, as we said, we gave 2021 guidance. We’re not going to</p>

	<p>give a quantitative guidance for '22 and '23. That's going to come at a later point, where we have the ability to really build this bottom-up with quality. Everything we're going to give to you is with quality.</p> <p>But what we can say and that you see that in the slides, the ones that we quoted and others, is that <b>we have all the levers in place now to be very confident to say that '21 is a trough year.</b> And as Sanjeev just said, <b>a trough year on revenue, a trough year on EBITDA and definitely a trough year on cash flow.</b></p> <p><b>Statement No. 3</b></p> <p><b>No, and look, one of the reasons we wanted to make sure, first of all, you guys get comfortable about the '21 being the trough year.</b> That was one of the objective[s] today.</p>
<p>March 10, 2021 Barclays Global Healthcare Conference 2021</p>	<p><b>Statement No. 12</b></p> <p>Well, I think what we consistently said is that the focus is on -- in the first 3 years is on rebalancing and de-levering. That's where our priorities lie. <b>We also very consistently said that we see 2021 as a trough year. Now trough year clearly means it's not going to go lower than this, right?</b> And we say trough year, that's for revenue. That's for EBITDA. And it's more certainly for cash flow, right? For cash flow, you can clearly see -- you don't need to believe in anything else to see that the cash flow will grow as the onetime costs kind of start diminishing.</p>
<p>May 10, 2021 Quarter 1, 2021 Earnings Call</p>	<p><b>Statement No. 14</b></p> <p>... [W]e are reaffirming our full year financial guidance for 2021, which incorporates the known potential headwinds and tailwinds for the remainder of the year. At the conclusion of the second quarter, we will be reassessing whether to update guidance for the full year. And while we're not giving long-term guidance at this time, <b>we continue to feel strongly that 2021 is our trough year as defined by the midpoint of our guidance of USD 6.2 billion adjusted EBITDA. And we believe that, that \$6.2 billion is a true floor of our business, not just for this year but also for future years.</b></p>

<p>May 18, 2021 RBC Capital Markets Healthcare Conference</p>	<p><b>Statement No. 15</b></p> <p>Look, what we said is, again, we're not giving guidance at this point. <b>But the 6.2[] as a floor, we're highly, highly confident in because we know all the levers that we can have. We know the robustness of our business and our EBITDA you can put any leverage.</b> Free cash flow, high confidence again because <b>we clearly see the growth coming driven by EBITDA</b> and lower onetime costs. On revenue, we've got a good understanding of the base erosion that we have in the business. <b>We have a good understanding of the new pipeline revenue we can bring.</b> But if you look at it quarter-on-quarter or even year-on-year, it can be a bit choppy because of things like COVID, for example, or because of URP China timing. If that gets further delayed, that would change a little bit how '21 over '22 develops.</p> <p><b>Statement No. 17</b></p> <p>You've seen us meeting our financial commitments. We're going to continue to do that, including declaring a dividend, paying down our debt and on track to deliver on our synergies. We are reaffirming our full year 2021 guidance. And as we said, after the end of Q2, we're going to look at that again and reassess whether we would update that guidance. <b>We continue to remain confident that '21 is our trough year. And we gave a definition of that. The definition is \$6.2 billion in EBITDA as our floor going forward.</b></p> <p><b>Statement No. 19</b></p> <p>So let me back up and talk about the trough year question and kind of the outlook for the business first. .... No, we're not giving long-term guidance. We're very clear about that. We're committed to giving some color on that towards the end of the year. But what we did always say is <b>this trough year term, that '21, we see that as a trough year. And we also get a lot of question on what that means. So at the earnings, we actually defined what that means by saying, we have a midpoint of our adjusted EBITDA guidance for the year, that's \$6.2 billion. And then we believe that, that \$6.2 billion is the floor for our business going forward. So that's about as hard as a line as you can draw at this point.</b> And we're confident in that for a number of reasons.</p>
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<p>June 10, 2021 Goldman Sachs Healthcare Conference</p>	<p><b>Statement No. 21</b></p> <p>So that gives us a good feeling, and that's just top line. So from there, you go down, and you know <b>all the levers that we have to go between revenue and EBITDA. So it gives us high confidence to be able to make that statement of \$6.2 billion being the floor for the business going forward.</b></p> <p><b>Statement No. 28</b></p> <p>[W]e see this as a kind of a 2-horizon kind of strategy, where you have the first horizon, maybe around 3 years and the second horizon. In that first horizon, our priority clearly is on delevering and rebalancing that business that we have, right? We really have great building blocks to build to it. <b>But putting it all together, that means we see 2021 as our trough year. We consistently said that. We recently defined what that means to be a trough year. That means the midpoint of our guidance of \$6.2 billion being the floor of our business going forward.</b></p> <p><b>Statement No. 29</b></p> <p><u>Nathan Allen Rich (Goldman Sachs Group, Inc.)</u> I guess as we think about going from this trough this year to beyond that, starting next year, what do you feel like are the key swing factors that investors should have in mind when they think about their model, both on the positive and headwind front that will determine kind of their growth in 2022 and 2023?</p> <p><u>Michael Goettler</u></p> <p>So we're not giving long-term guidance, <b>as you know, we kind of defined the floor. We're going through our strategic plan process. We'll let that play out, and we're committed to giving a bit more color at the end of the year.</b></p> <p>But what gives us confidence in the 6.2 number is that we understand what these headwinds and tailwinds really are. We know what's at our disposal. . . . But let me just walk through kind of if you look at the revenue, right, you have to realize that we have a much more diversified revenue base, right? And that helps us to absorb any kind of headwinds that we signed in any particular part of the business. We do understand very well what our base business erosion is. . . .</p>
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<p>August 9, 2021 Quarter 2, 2021 Earnings Call</p>	<p><b>We also understand what our pipeline can contribute, right?</b> You take all of that together, and then we have the potential for revenue synergies. None of that baked into any numbers, but the potential is clearly there. So that gives you kind of the revenues. . . . Then gross margin, we're very, very disciplined about how we rationalize our portfolio. That's an ongoing process that allows us to have some benefit on the gross margin as we rationalize the portfolio. And then last but not least, on SG&amp;A, we get synergies. <b>We typically have multiple levers, right, to continue to deliver, have confidence in that \$6.2 billion adjusted EBITDA as a floor. And then again, later in the year, we'll get more color on that.</b></p> <p><b>Statement No. 30</b></p> <p><b>[O]n last earnings call, I stated that we see \$6.2 billion in adjusted EBITDA as a true floor of our business going forward and with the momentum we have, this is now clearer than ever."</b></p> <p><b>Statement No. 40</b></p> <p>But on the '22 question, let me just reemphasize again what I also said in my prepared remarks is that we really see the <b>\$6.2 billion true floor for this business. I think with the performance we have under our belt now from both the first and the second quarter, it's more clear than ever to us that that's the case.</b></p> <p><b>Statement No. 42</b></p> <p>We've raised the guidance for 2021. <b>And I want to reiterate again, \$6.2 billion is the true floor of this business in terms of adjusted EBITDA, and that's more kind of at or above that level going forward. And lastly, we've embarked on a robust bottom-up work will complete by the end of the year, and we look really forward to communicating that with you when it's completed.</b></p> <p>September 10, 2021 Citi Biopharma Conference</p> <p><b>Statement No. 43</b></p> <p>I think we have to go back to what I actually said in the second quarter conference call. What we said is that is at that time, <b>\$6.2 billion of adjusted EBITDA as a floor –as a true floor of our</b></p>
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<p>November 8, 2021 Quarter 3, 2021 Earnings Call</p>	<p><b>business going forward</b> based on everything we saw at that time. This is not guidance for 2020, right. This is meant to be a support. It's meant to be <b>a floor in the interim period while we are working on our long-term outlook, while we are working on our strategic plan. And until we give guidance for '22 and years beyond, this was meant to be a helpful floor and information. That's what the \$6.2 billion is.</b></p> <p><b>Statement No. 52</b></p> <p>On the last quarter's earnings call, we said we would reevaluate our 2021 financial guidance at the end of the third quarter. Based on our strong performance to date, we are, again, raising our financial guidance across total revenue, adjusted EBITDA and free cash flow, which Sanjeev will discuss in more detail later. I'm also pleased to say that we are near completion of our rigorous bottom-up strategic planning effort.</p> <p>We look forward to sharing the results of these plans with the investment community at a virtual investor event now scheduled for the morning of January 7, 2022. And on that day, we'll provide additional details on our 2-phase strategic road map, including for the rest of Phase I, that is the years 2022 and 2023, we'll be providing specific financial guidance, targets and metrics to complete this phase. We'll also be discussing the substantial free cash flow that we will be generating over this period to satisfy our Phase I capital allocation priorities of returning capital to shareholders and of repaying \$6.5 billion of debt. And with that said, <b>we continue to remain confident that \$6.2 billion of adjusted EBITDA is the true floor of our business.</b></p> <p><b>Statement No. 53</b></p> <p>Schott: I ... appreciate the comment on, I think it was \$6.2 billion in EBITDA as a floor for the business. I guess my question here was, I think in the past, you've talked about 2021 as a trough number. I know you've raised the guidance a few times have gone through (sic) this year. So let me just understand a little bit what's going on here. Some of the upside we're seeing, I guess, more onetime in nature this year. Or are there any other factors that contribute to that dynamic? I'm just trying to kind of bridge between, I guess, a new midpoint of \$6.4 billion versus that floor \$6.2 billion....</p> <p>Goettler: ...On the EBITDA question you have, clearly, we're not</p>
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<p>December 1, 2021 Evercore ISI HealthCONx Conference</p>	<p>giving guidance today. We're very, very pleased with the performance that we have, now 3 consecutive quarters. <b>We strongly feel that we stabilize this business. We got a good handle on the business. We now finished or almost finished the bottom-up rigorous strategic planning process. And with that, we're reconfirming again what we said before, the \$6.2 billion is the floor</b></p> <p><b>Statement No. 60</b></p> <p><u>Sanjeev Narula</u></p> <p>Now the impact on EBITDA, obviously, we'll talk about that on January 7, but we also have the synergy flow-through that's going to happen this year, next year and the year after that. So obviously, you've got to keep that in mind to figure out. As Michael pointed out, I think, <b>the key thing to note about it is the \$6.2 billion is the floor.</b> And rest of all that, what the number comes out is probably something that we'll talk about at the Investor Day on January 7.</p> <p><u>Umer Raffat (Evercore ISI)</u></p> <p>Got it. So it sounds like <b>there's enough levers in the business to pull to ensure that EBITDA strength -- EBITDA momentum continues even while absorbing impact from a gross margin pressure. Am I hearing that right?</b></p> <p><u>Sanjeev Narula</u></p> <p><b>I think – yes[.]</b></p> <p><b>Statement No. 61</b></p> <p>Yes, we're not giving guidance, but <b>the \$6.2 billion is the floor and we're confident in that.</b></p>
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Defendants argue that the above statements are “forward-looking”; and, as such, protected under the Safe Harbor provisions. Specifically, Defendants characterize these statements as quintessential examples of forward-looking, because they are projections of revenues and the future economic performance of the company.



Plaintiffs maintain that Defendants lacked a reasonable basis to make these projections, because Defendants statements omitted that Viatrix was conducting a “thorough strategic review” in which Defendants were actively and seriously considering whether parts of the business were “core” or “noncore.” Therefore, Plaintiffs maintain that Defendants lacked sufficient information to know whether the Company’s future adjusted EBITDA would fall above or below \$6.2 billion.

The term “forward-looking statement” is broadly defined in the statute to include statements “containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items”; statements of “the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer”; or statements of “future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission.” 15 U.S.C. § 78u–5(i)(1)(A)–(C). This safe harbor is designed to shield statements, like those regarding revenue projections and future business plans, from leading to liability. *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 272 (3d Cir. 2005). However, “revenue projections are susceptible to attack on the ground that it was issued without a reasonable basis.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1427 (3d Cir. 1997).

In *Williams v. Globus Medical, Inc.*, 869 F.3d 235, 244 (3d Cir. 2017), the Third Circuit affirmed the district court’s grant of a motion to dismiss, where the plaintiff failed to plead facts to cite to contemporaneous sources to show that defendants had knowingly incorporated revenue that was premised upon a continuing relationship with one of its distributors; however, the

Defendant subsequently terminated said relationship. The Third Circuit determined that “plaintiffs rel[ied] on conjecture based upon subsequent events.” *Id.* at 245. Further, the Third Circuit stated that, even if defendant Globus “knew or should have known that ending its relationship with [the terminated distributor] could have some effect on its sales...Plaintiffs have not pleaded any facts to support their claim that Globus incorporated anticipated revenue from [the distributor] in its projections.” *Id.* at 246.

Here, Plaintiffs’ Amended Complaint lacks sufficient specificity that would plausibly circumvent the Defendants’ Safe Harbor assertion that statements 1, 2, 3, 12, 14, 15, 17, 19, 21, 28, 29, 30, 40, 42, 43, 52, 53, 60, and 61 are “forward-looking” revenue projections. At the motion to dismiss stage, Plaintiffs must adequately plead that these forward-looking projections were issued without a reasonable basis. Plaintiffs’ argument relies on the premise that Viatrix could not reasonably project revenue in light of its ongoing strategic review. However, Viatrix, in its SEC filings, (1) did disclose its ongoing strategic work and did describe the breadth of that work; and (2) it expressly cautioned that it was continuing to consider divestitures, including potentially material divestitures. (ECF No. 56-1 at p. 7, 8, 21).

In examining the subject statements, all signal and communicate the potential for “plans and objectives for future operations, including the plans and objectives relating to the products or services.” See 15 U.S.C. § 78u–5(i)(1)(B). Said statements included potential for major changes, including a fair representation that Defendants’ ultimate plan included impacts based upon market share and divestitures. Further, the statements consistently represented no predictions for 2022 and beyond. Instead, the statements examined only 2021 predictions and informed that, later in 2021, Defendants would make further predictions for future years, 2022 and 2023. Moreover, Defendants generally couched their statements, regarding any predictions

beyond 2021 in terms such as “believe” and “confident.” Defendants also reiterated that their floor predictions were meant to be helpful, since they could not give guidance for 2022 and beyond because they were working on a strategic plan. *See* Statement No. 43. Defendants later stated that they would give more details in 2022 regarding a 2-phase strategic roadmap that would outline specific financial guidance, targets, and metrics. *See* Statement No. 52.

Therefore, contemporaneous sources, namely SEC documents filed at the time of the challenged statements, supported Defendants’ view of the business and presented reasonable bases for Defendants’ to make their 2021 revenue projections. Further, at a fundamental level, the Amended Complaint relies upon conjecture by Plaintiffs in their assessment of Defendants’ statements and the subsequent decision to pursue the biosimilar business sale. The Amended Complaint fails to plead a nexus between said sale and Defendants’ “forward-looking” revenue projections.

Accordingly, the Safe Harbor provisions apply to statements Nos. 1, 2, 3, 12, 14, 15, 17, 19, 21, 28, 29, 30, 40, 42, 43, 52, 53, 60, and 61 as set forth in Plaintiffs’ Amended Complaint.

#### **b. Future of Biosimilars**

<b>Context</b>	<b>Statement Nos. 5, 6, 7, 8, 10, 11, 26, 27, 37, 38, 39, 44, 48, 50, 51, 54, and 57</b>
March 1, 2021 Viatis Inc. Analyst/Investor Day Call	<p><b>Statement No. 5</b></p> <p>We also <b>continue to remain committed to invest in the biosimilar development programs.</b> And Walt will talk in a lot of detail about our biosimilar pipeline, where we are with the pipeline, with the development programs. But I would just like to highlight that we will be <b>extremely focused on our efforts to be the first to the market and believe we are well positioned for several of our key programs in the future.</b></p> <p><b>Statement No. 6</b></p> <p><u>Balaji V. Prasad (Barclays Bank PLC):</u></p>

Firstly, on the biosimilars front. Can you tell us if you have enough pipeline currently now with the second and third wave portfolio of biosimilars, and you need to augment this with newer partnerships? Also, if you can help us call out the ROCI you generate on biosimilars today and directionally, where could this move to? I'm asking this in particular context with one of your competitors signaling exit from the biosimilar strategy indicating that this is not as attractive as it was thought 2 years ago or 1 year ago. . . .

Michael Goettler:

Thanks, Balaji, and let me just summarize. **We have no intention to get out of biosimilars, quite the opposite.** But let me have Rajiv get more into details on that.

#### **Statement No. 7**

Thanks, Balaji, and thanks, Michael. Balaji, we today try to show you a little bit about what not we have only achieved, but more importantly, what's in the pipeline. And we're excited, as we already disclosed with the projects like looking into the biosimilar to Avastin, looking to the biosimilar of NovoLog, EYLEA, biosimilar to Humira, biosimilar to Perjeta, Toujeo, BOTOX, I can go on.

And as we're talking about this, you would expect us that Walt talked about certain targets, and that's where exactly where we are wider near the program, finalizing the diligence around that. And we will continue to go both ways. We will keep on looking for the partnerships, and we'll keep on building our own competencies.

So it's an area for us where we have said this is a global franchise. **This is an area where we have decided to hang in, not get out. And for us, it's a long-term play, and we continue to make the R&D investments, as well as investments in our commercial infrastructure. Because we are very excited what we see ahead in this growing space. So that's my two cents view on the biosimilars.**

#### **Statement No. 8**

The second building block on this road map is focused growth. I will talk to you about our focus on highly profitable, highly complex products. **You will see our global business and biosimilars continue to be a long-term investment strategy.**

<p>March 10, 2021 Barclays Global Healthcare Conference 2021</p>	<p>And we project growth in this franchise in both developed market regions on a year-over-year basis.</p> <p><b>Statement No. 10</b></p> <p><u>Balaji V. Prasad (Barclays Bank PLC)</u></p> <p>Biosimilars, I mean, that's part of the business that I've always been very excited about. I like the platform and the broad [step] of the pipeline that you, Mylan, historically had and Viartis has. So I get it when you speak to the global gateway, but why not take on unpartnered approach, especially (inaudible) being so massive and you're bullish on it. And why don't you go on it on your own instead of having like 5 or 6 partners for your 15, 16 products?</p> <p>Rajiv Malik So Balaji, it's a great question. And as you know, we – <b>it's a strategic area for us. And if it's a strategic area, we will be looking forward to build the core competencies, which we have been working on. And our first core competency, which we have been building upon, has been in our science side, R&amp;D side, regulatory, medical affairs, which we have been building up.</b></p> <p>Now still partnership continues to be a sort of -- for us, it has worked very well. These are deep partnerships. These are not one-off products. Our partnership with Biocon is more of a strategic sort of relationship, and I think we have done pretty well in executing that. Of course, the FKB one is -- which is one around the biosimilar (inaudible) full year is one of -- where it's one product opportunity. But I tell you that there's enough capacity available, as you know, from the manufacturing point of view. So building our own -- allocating our own CapEx to build that today perhaps is not the smartest way to allocate our capital when we have very -- many other priorities very well defined. <b>But you can be rest assured, because if this is a strategic area for us, we will be building those components as we go along, starting with the science and, more importantly, what we need to enhance and build on our commercial site. And what are those areas so that we can get more out of this platform?</b></p>
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**Statement No. 11**Balaji V. Prasad (Barclays Bank PLC)

[O]n the question of biosimilars. Can you help us understand how should -- how we need to think about competition in the space? There are not too many players globally who would want to be global biosimilar players, right, who are -- were in that capacity. And I can also see the advantage partners having partners from other economies or geographies (inaudible). And Sandoz just came out recently, an hour ago maybe, saying that they expect biosimilars to be a major growth engine for them globally. And what would competition entail for you? And is it going to be where you vastly talk on losing economics as it happened in the generic side? Or is this going to be much more impact to opportunity?

Rajiv Malik

I think we always said that **biosimilar for us is not a U.S.-specific business or a market-specific business. For us, it's a global franchise.** And we -- I gave in my Investor Day, I gave example of one Herceptin biosimilar being launched from one country and today being in 65 countries.

And you're so right, there is no global competition. Yes, Sandoz is now shaping up as a global sort of competitor, but many of these markets, especially the emerging markets, there are -- this is something which you can't play much locally. Now, of course, there is a competition coming in from some of the Indian biosimilar players, which we will have that, but I think we have the advantage that -- from our partners point of view, that we have the infrastructure to take it to the -- any part of the world, right from the China to the Latin America, to the Africa. So that's the advantage of partnering with somebody like us.

And I'll tell you, our commercial infrastructure in these markets enables us to get more of this platform in -- just starting with what we have -- already what we have. **And we see that this will continue to be one of the key growth drivers as we launch more and more of these products in more geographies.**

<p>June 10, 2021 Goldman Sachs Healthcare Conference</p>	<p><b>Statement No. 26</b></p> <p>Nathan Allen Rich (Goldman Sachs Group, Inc.)</p> <p>But with the base business erosion, can you maybe talk about the components of that? Why you feel comfortable that 3% to 4% is the right number? And how that maybe breaks down across the different businesses that you have when we think about brands, generics and complex products and biosimilars?</p> <p><u>Sanjeev Narula</u></p> <p>I think you need to understand and appreciate what is driving that. And one is this, the resilience. 60% of this is brands, 30% is generics and 10% is complex and biosimilars today. <b>And it's moving more towards the complex and biosimilars. . .</b></p> <p>. . . .</p> <p><b>Now pocket of biosimilars is growing. As you saw, Q1 was 27% growth in that bucket of complex and biosimilars. That's very much all the biosimilar growth, 27% worth of biosimilars growth.</b></p> <p><b>Statement No. 27</b></p> <p><u>Nathan Allen Rich (Goldman Sachs Group, Inc.)</u></p> <p>Could you maybe help us think about across the different areas, biosimilars, complex products, injectables, sort of the relative sizes of the opportunities and maybe what you're most excited about in terms of coming to market over the next several years?</p> <p><u>Rajiv Malik</u></p> <p>A lot of opportunities in this pipeline. <b>And over a period of time, it is moving from value chain perspective. Today, almost 75% of our portfolio is around complex and biosimilars.</b> We are not moving away from generics, but we have been smart about that. We have been diligent about that, that how we pick our spots and compete in that.</p> <p>So when it comes to the biosimilars, I think next couple of years, will be an opportunity like -- and I'm excited by EYLEA. I think we are still -- because as you've seen by this time, not in U.S.A., everywhere else also, <b>the first to market is becoming a decisive</b></p>
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<p>August 9, 2021 Viatis Inc. Quarter 2, 2021 Earnings Call</p>	<p><b>advantage. And that's where our -- we want to focus on, how can we be the first to the market.</b> And EYLEA is -- we just had a successful readout of our Phase III. We are in very much as we have said that we'll be filing this we are able -- within this year. We remain on track. That's one.</p> <p>BOTOX is very exciting for us because, <b>again, we are leading the pack over here</b>, having good engagement with the FDA. FDA is excited that there are some restocking about bringing another biosimilar over here. So I think that's building up.</p> <p><b>Statement No. 37</b></p> <p>Our Developed Markets segment grew by 2% year-over-year. . . . <b>Our biosimilars performed strongly with 47% growth this quarter, which helped offset the negative impact of the previously anticipated competition to Wixela and XULANE.</b> Our generics portfolio also performed better than our expectations, primarily driven by our U.S. injectables portfolio, as well as favorable COVID-related buying patterns in Europe. Having said that, <b>we see our biosimilars portfolio driving continued growth while offsetting anticipated competition in our complex generics space.</b></p> <p>. . .</p> <p>It can take, on average, 7 to 9 years from development to regulatory approval, given the highly complex nature of these molecules. Getting to the finish line requires tremendous perseverance, tenacity and an unwavering commitment to patients. The success stories of receiving the first approval for our Copaxone 40-milligram, Advair, Neulasta, Herceptin, Symbicort, and <b>most recently, the first interchangeable biosimilar to the Lantus, give us great confidence that we are well positioned to deliver on our pipeline.</b> We intend to leverage our deep scientific capabilities to further expand access to the complex products for patients.</p> <p><b>Statement No. 38</b></p> <p>[L]et me just back up and make maybe a general comment here is that <b>EYLEA, to me, this -- the interchangeability on Lantus, I mean, these are all proof points, I think, that we have that our biosimilar portfolio is strong. It's going to be a driver of growth going forward and something to be very proud of, right?</b> The approval of Semglee (inaudible) is historic. And</p>
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<p>September 10, 2021 Citi Biopharma Conference</p>	<p>EYLEA, look, we're -- the number of competitors going into it, we're leading right now. And we're the first one to finish clinical trial, and we feel very proud about this.</p> <p><b>Statement No. 39</b></p> <p>Yes. And one other question was about how difficult is interchangeability, and I would say, look, Gary, ideally suited products for interchangeability of a chronically administered biosimilars where disease needs to be relatively stable and with a limited chance of rapid decline, and it's a case by case. And it does include -- the current guidance across for the biosimilars on interchangeability includes pharmacokinetic equivalence after 3 switches of test reference, test versus the reference product. So there is additional work and science involved. . . .</p> <p>Our goal would be to basically drive the excess, and we believe that the substitution at the pharmacy level will help us drive that. And we see, from a timing perspective, we see some -- you will see some uptick in the market share around quarter 4, but the actual and the decent impact of interchangeability to the market share perspective and excess will be seen over the next year.</p> <p><b>For us, I see this as a long-term opportunity with a long tail.</b> And interchangeability -- and just one thing I've missed, I think, on your question around how long, we do have 12-month exclusivity for any other interchangeable product to come.</p> <p><b>Statement No. 44</b></p> <p><u>Navann Ty (Citi)</u></p> <p>Switching to business development. What is -- maybe staying on the credit profile. What is the gross leverage -- is there a gross leverage level that Viartis should reach before considering business development?</p> <p><u>Michael Goettler</u></p> <p>. . . And I think investors should not forget, in addition to BD, we -- or actually BD is the addition to the R&amp;D engine that we have. We have a strong internal R&amp;D engine. So we actually -- especially in biosimilars, complex generics. <b>So we're actually in a position to be very disciplined. We're in a position to be very choosy and only add the right deals when we see them.</b> But don't mistake our commitments for lack of activity and interest [in</p>
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this business area].

**Statement No. 48**

**Biosimilar[s] is and will continue to be an important area for the company and will be a key growth driver, a key driver for our future growth.** And let me also say, it's a little bit too early in the biosimilar space as this market is evolving, as it's in its infancy that we should say that we should not go on the predicting game of the winners and losers.

**Statement No. 50**

And then the second part is as we have gone around the world, launched these products, starting with the U.S.A., Europe and many other emerging markets, we're having -- we had many learnings. And it's not just contractual game as game -- as product life cycle evolves, you need more than the contractual capabilities, and we are mapping those. We are building those capabilities as we go along. And I remain very, very optimistic that it's -- we have done pretty well from a science point of view. We have done -- we have a mixed bag from the commercial execution point of view. We have several successes Toujeo in Japan. First Herceptin in Australia, Canada. First Fulphila, which is a biosimilar. Neulasta in U.S.A. **So we have some several key successes, and I think we're going to build upon that.**

**Statement No. 51**

Yes. I think, Rajiv, you hit on the key points. And maybe what I can add is from a strategy perspective, it's very clear that biosimilars is not a mature market yet, and it's a growing market. **There's no doubt about it. And therefore, with the capabilities we have, it is and will be and can be a growth driver for Viatris.**

We've made significant investments in building the pipeline. We've shown that we can deliver on the science and bring these innovative products to the market. We have only a few molecules now, but already these few molecules are 150 marketing authorizations in 85 countries. So it shows our ability to take this and really take a global approach to it.

And we have, and Rajiv mentioned a few examples, we have one of **the most diverse and strongest pipeline in biosimilars to follow that. So what that means is in the future, that portfolio,**

<p>November 8, 2021 Viartis Inc. Quarter 3, 2021 Earnings Call</p>	<p><b>that pipeline will translate into a commercial portfolio and gives us one of the strongest commercial portfolios in the industry. I believe that having that broad portfolio is actually important.</b></p> <p>So I agree with Rajiv. It's too early to declare winners and losers in the market. It's a developing market. <b>And you should fully expect us, again, as part of the strategic plan process that we'll look into the biosimilar opportunity very deeply, and then we consider it, and we'll make it a significant source of growth for Viartis going forward.</b></p> <p><b>Statement No. 54</b></p> <p>Before I get into the quarter at hand, I would like to echo Michael's excitement about our upcoming investor event. What you can expect to hear from me is a comprehensive review of the <b>significant value and the depth of our pipeline and clinical programs, including biosimilars</b>, complex generics and our medicines <b>that we have been strategically building over many years. These development programs are expected to play a significant role in our ability to drive organic growth over time</b>, especially as our cost synergies roll off at the end of 2023. Once laid out in January, <b>we believe our pipeline will be recognized as one of the company's most underappreciated assets</b> that will enable us to continue to deliver value while fulfilling our mission of expanding access and addressing patient needs.</p>
<p>December 1, 2021 Evercore ISI HealthCONx Conference</p>	<p><b>Statement No. 57</b></p> <p><u>Umer Raffat (Evercore ISI)</u></p> <p>I know from a business perspective, the Street expectations on your business are sort of in 2 phases right now. There is a near-term phase where business is being modeled to be flattish, and then there's a post '23 phase when some of the investments historically from the R&amp;D organization in the biosimilar starts to set the case for growth. Is that consistent with how you guys think about it? And how does that translate from an EBITDA perspective near term versus post '23?</p> <p><u>Michael Goettler</u></p> <p>We think of it also in 2 phases. We look at it in the Phase I where our commitments are very, very clear, and then a Phase II. We're</p>

	<p>not giving guidance today. Obviously, we're going to lay out on our Investor Day exactly how we deliver on our commitments for Phase I. <b>And then we're going to give you the catalyst for the growth in Phase II. And the catalysts are our pipeline, which we think is underappreciated. We've got some very strong investments in biosimilars, in complex generics that will drive it.</b> We're going to talk about our capital allocation priorities for that time and how we unlock value for shareholders. <b>And I think the pipeline is really key.</b></p>
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Defendants argue that statements regarding the biosimilars business were identified as forward-looking in Viatri's SEC filings and, because the statements are "plans and objectives . . . for future operations, including plans or objectives relating to the [Company's] products," they are forward-looking.

Plaintiffs contend that Defendants' statements were misleading because Defendants did not disclose that: (1) Defendants had decided, as part of the 2021 Strategic Review, that biosimilars were "noncore" to Viatri's future and thus should be sold; and (2) Viatri had concrete plans to sell its biosimilars business. Therefore, Plaintiffs maintain that, by continuing to tout Viatri's business model and biosimilars growth strategy, Defendants had a duty to disclose that the company had transformed its business model after finding that biosimilars was, in fact, "noncore" to Viatri's future.

Defendants respond that Plaintiffs have pleaded no facts to support that, by November 8, 2021, "whatever the status of [Viatri's] negotiations [with Biocon], Viatri had decided that biosimilars were noncore and had concrete plans to sell the business."

Under the Safe Harbor statute, a "forward-looking statement" includes, "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer," as well as "any statement of the assumptions

underlying or relating to any” forward-looking statement. 15 U.S.C. § 78u–5(i)(1)(B),(D). At least one court has held that a protected forward-looking statement might include such statements reflecting a company’s plans or objective are not promises to maintain that policy in the future. *See San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Companies, Inc.*, 75 F.3d 801, 811 (2d Cir. 1996). Thus, the Second Circuit concluded that a company’s subsequent consideration of an alternative plan was not actionable. *See id.* Likewise, Courts have rejected allegations of “fraud by hindsight.” *See High Income Sec. Fund v. Cedar Realty Tr., Inc.*, 2023 WL 6214237, \*8 (E.D.N.Y. Sept. 25, 2023) (rejecting as ““fraud by hindsight”” the claim that a potential transaction in January 2022 showed statements in August and September 2021 were false); *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000); *see also San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 812 (2d Cir. 1996) (affirming dismissal of securities fraud claims where plaintiffs failed to allege facts “demonstrating that during the class period [the defendant] was doing anything but pursuing [its expressed] strategy,” or that defendant “made any statements or predictions foreclosing the possibility of adopting alternative marketing strategies”); *In re Kirkland Lake Gold Ltd. Sec. Litig.*, No. 20-CV-4953, 2021 WL 4482151, at \*4–5 (S.D.N.Y. Sept. 30, 2021) (rejecting plaintiff’s allegations regarding acquisition as “fraud by hindsight” because challenged statements “were not false when made, made no explicit promises, and did not foreclose a future acquisition”).

Here, the Amended Complaint alleges a conclusory assertion that Viatris must have decided to divest biosimilars, because the strategic planning process was “almost finished” in early November 2021 and the Biocon transaction was announced on February 27, 2022, 110 days later. Absent pleading plausible facts, the temporal proximity between the “near completion” of

the strategic review in November and the Biocon transaction in February 2022 does not meet Plaintiffs' burden that Defendants' statements were not forward-looking business plans and objectives protected under the Safe Harbor statute. Nothing in the Amended Complaint connects a non-speculative, plausible theory that the Biocon transaction was definitively in Defendants' minds during the relevant period. Further, such statements were coupled with "meaningful cautionary statements" through clear disclosures of a strategic review that included potential material divestitures of products and business on an ongoing basis and that such divestitures could reduce the size or scope of Viatri's businesses.

Accordingly, the Safe Harbor provisions apply to statements Nos. 5, 6, 7, 8, 10, 11, 26, 27, 37, 38, 39, 44, 48, 50, 51, 54, and 57 as set forth in Plaintiffs' Amended Complaint.

**c. Product Pipeline and Portfolio Statements**

<b>Context</b>	<b>Statement Nos. 4, 11, 13, 20, 24, 29, 34, 36, 37, 41, 47, 49, 50, 51, 54, and 57</b>
March 1, 2021 Viatri's Inc. Analyst/Investor Day Call	<p><b>Statement No. 4</b></p> <p>Our goal over the last few years has been to move up the value chain from a science perspective. The complex generics and the biosimilars require, not only just high R&amp;D spend, I think it requires a high level of the science, more complex science, executing through that complex science, regulatory strategy, IP legal skill sets. And I believe we have already shown that we have those core competencies to excel in this space through some first-to-market successes like generic Advair, generic to the Advair, generic to the Copaxone, biosimilar to Neulasta, biosimilar to Herceptin, and I can go on.</p> <p>While we are very proud of our track record, we also believe that we can do a lot more in this space and better serve the patient needs by breaking down these barriers. <b>These investments have enabled us to see durable long-term revenue streams as compared to the core generics. And we see this as a core part of our forward-looking Viatri's portfolio.</b></p>

<p>March 10, 2021 Barclays Global Healthcare Conference 2021</p>	<p><b>Statement No. 11</b></p> <p><u>Balaji V. Prasad (Barclays Bank PLC)</u></p> <p>[O]n the question of biosimilars. Can you help us understand how should -- how we need to think about competition in the space? There are not too many players globally who would want to be global biosimilar players, right, who are -- were in that capacity. And I can also see the advantage partners having partners from other economies or geographies (inaudible). And Sandoz just came out recently, an hour ago maybe, saying that they expect biosimilars to be a major growth engine for them globally. And what would competition entail for you? And is it going to be where you vastly talk on losing economics as it happened in the generic side? Or is this going to be much more impact to opportunity?</p> <p><u>Rajiv Malik</u></p> <p>I think we always said that <b>biosimilar for us is not a U.S.-specific business or a market-specific business. For us, it's a global franchise.</b> And we -- I gave in my Investor Day, I gave example of one Herceptin biosimilar being launched from one country and today being in 65 countries.</p> <p>And you're so right, there is no global competition. Yes, Sandoz is now shaping up as a global sort of competitor, but many of these markets, especially the emerging markets, there are -- this is something which you can't play much locally. Now, of course, there is a competition coming in from some of the Indian biosimilar players, which we will have that, but I think we have the advantage that -- from our partners point of view, that we have the infrastructure to take it to the -- any part of the world, right from the China to the Latin America, to the Africa. So that's the advantage of partnering with somebody like us.</p> <p>And I'll tell you, our commercial infrastructure in these markets enables us to get more of this platform in -- just starting with what we have -- already what we have. <b>And we see that this will continue to be one of the key growth drivers as we launch more and more of these products in more geographies.</b></p>
<p>May 10, 2021 Viartis Inc. Quarter 1, 2021 Earnings Call</p>	<p><b>Statement No. 13</b></p> <p>This quarter, we generated USD 163 million in new product revenue to partially offset inherent product erosion, and we're on</p>

<p>May 18, 2021 RBC Capital Markets Healthcare Conference</p>	<p>track to achieve USD 690 million in new product revenue for the full year. <b>We're continuing to shift to more differentiated and sustainable portfolio with strong growth in complex generics and biosimilars and growth of our recently acquired thrombosis franchise in Europe.</b></p> <p><b>Statement No. 20</b></p> <p>Number one is <b>we know the robust business model that we have.</b> Now that's <b>balanced, that's diversified.</b> We can <b>absorb the headwinds and tailwinds.</b> So we have high confidence in that, and again, our first quarter results reflect that. We understand the <b>base business that we have and the natural erosion that we have in that base business.</b> We understand what our pipeline can deliver.</p>
<p>June 10, 2021 Goldman Sachs Healthcare Conference</p>	<p><b>Statement No. 24</b></p> <p>A strong R&amp;D platform that is proven, well positioned to deliver <b>a broad pipeline of complex and novel products, including our late-stage biosimilars</b> and we have over 10 biosimilars in development in oncology, ophthalmology, immunology, diabetes and others.</p> <p><b>Statement No. 29</b></p> <p><u>Nathan Allen Rich (Goldman Sachs Group, Inc.)</u></p> <p>I guess as we think about going from this trough this year to beyond that, starting next year, what do you feel like are the key swing factors that investors should have in mind when they think about their model, both on the positive and headwind front that will determine kind of their growth in 2022 and 2023?</p> <p><u>Michael Goettler</u></p> <p>So we're not giving long-term guidance, <b>as you know, we kind of defined the floor. We're going through our strategic plan process. We'll let that play out, and we're committed to giving a bit more color at the end of the year.</b></p> <p><b>But what gives us confidence in the 6.2 number is that we understand what these headwinds and tailwinds really are. We know what's at our disposal. . . . But let me just walk through kind of if you look at the revenue, right, you have to realize that we have a much more diversified revenue base, right? And that</b></p>



<p>August 9, 2021 Viatris Inc. Quarter 2, 2021 Earnings Call</p>	<p><b>helps us to absorb any kind of headwinds that we signed in any particular part of the business.</b></p> <p>We do understand very well what our base business erosion is. . . .</p> <p><b>We also understand what our pipeline can contribute, right?</b> You take all of that together, and then we have the potential for revenue synergies. None of that baked into any numbers, but the potential is clearly there. So that gives you kind of the revenues. . . .</p> <p>Then gross margin, we're very, very disciplined about how we rationalize our portfolio. That's an ongoing process that allows us to have some benefit on the gross margin as we rationalize the portfolio. And then last but not least, on SG&amp;A, we get synergies. <b>We typically have multiple levers, right, to continue to deliver, have confidence in that \$6.2 billion adjusted EBITDA as a floor. And then again, later in the year, we'll get more color on that.</b></p> <p><b>Statement No. 34</b></p> <p>Lastly, and as I've already mentioned, I cannot emphasize enough the impressive R&amp;D engine and scientific capabilities that we have. <b>As we prepare to deliver our strategic plan, you can fully expect that we will continue to add high-value assets to our pipeline and further leverage our scientific expertise and R&amp;D platform.</b></p> <p><b>Statement No. 36</b></p> <p>Our global generics business grew by 8% year-over-year and performed better than our expectations. We delivered \$224 million for new launches in the second quarter. And as we look ahead, we remain on track to meet our \$690 million target in 2021. <b>We believe that the diversity of our portfolio and commercial reach positions us well to balance the impact of any changes in the market and eliminate our reliance on any one product or geography. Accordingly, we expect our base business to continue to perform strongly.</b></p> <p><b>Statement No. 37</b></p> <p>Our Developed Markets segment grew by 2% year-over-year. . . . <b>Our biosimilars performed strongly with 47% growth this quarter, which helped offset the negative impact of the</b></p>
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<p>September 10, 2021 Citi Biopharma Conference</p>	<p><b>previously anticipated competition to Wixela and XULANE.</b> Our generics portfolio also performed better than our expectations, primarily driven by our U.S. injectables portfolio, as well as favorable COVID-related buying patterns in Europe. Having said that, <b>we see our biosimilars portfolio driving continued growth while offsetting anticipated competition in our complex generics space</b></p> <p>....</p> <p>It can take, on average, 7 to 9 years from development to regulatory approval, given the highly complex nature of these molecules. Getting to the finish line requires tremendous perseverance, tenacity and an unwavering commitment to patients. The success stories of receiving the first approval for our Copaxone 40-milligram, Advair, Neulasta, Herceptin, Symbicort, <b>and most recently, the first interchangeable biosimilar to the Lantus, give us great confidence that we are well positioned to deliver on our pipeline.</b> We intend to leverage our deep scientific capabilities to further expand access to the complex products for patients</p> <p><b>Statement No. 41</b></p> <p>[W]e're outperforming at or above the upper end of our own expectation across the business. We feel good where we are. We're meeting our financial commitments. That includes the dividend. That includes the debt paydown. We're on track on synergies, and we're delivering very strong and sustainable free cash flow generation. I think this quarter has made that very visible. <b>We'll continue to make good progress on our pipeline, and Rajiv highlighted a few of those, including the historic approvals of assembly interchangeability.</b></p> <p><b>Statement No. 47</b></p> <p><b>So, if I look into our next 5 to 7 years, just to complement what Bill and Michael said, we have a very strong internal pipeline and as you know, execution around the science, clinical trials, the medical, regulatory as well as the IP legal and we have delivered it repeatedly whether it's a first to market opportunity on Wixela, Copaxone are not interchangeable delivering the first interchangeable biosimilar, which is assembly, so very exciting opportunities from pipeline point of view.</b></p>
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**Statement No. 49**

**The first part of our strategy is to build the portfolio because we believe having a deep and broad offering around commercial portfolio will ensure a robust strategy,** will be the first leg of delivering the strategy. And I just gave you several examples of our pipeline where we are either executed already or well on our way to execute on that.

**Statement No. 50**

And then the second part is as we have gone around the world, launched these products, starting with the U.S.A., Europe and many other emerging markets, we're having -- we had many learnings. And it's not just contractual game as game -- as product life cycle evolves, you need more than the contractual capabilities, and we are mapping those. We are building those capabilities as we go along. And I remain very, very optimistic that it's -- we have done pretty well from a science point of view. We have done -- we have a mixed bag from the commercial execution point of view. We have several successes Toujeo in Japan. First Herceptin in Australia, Canada. First Fulphila, which is a biosimilar. Neulasta in U.S.A. **So we have some several key successes, and I think we're going to build upon that.**

**Statement No. 51**

Yes. I think, Rajiv, you hit on the key points. And maybe what I can add is from a strategy perspective, it's very clear that biosimilars is not a mature market yet, and it's a growing market. **There's no doubt about it. And therefore, with the capabilities we have, it is and will be and can be a growth driver for Viatriis.**

We've made significant investments in building the pipeline. We've shown that we can deliver on the science and bring these innovative products to the market. We have only a few molecules now, but already these few molecules are 150 marketing authorizations in 85 countries. So it shows our ability to take this and really take a global approach to it.

And we have, and Rajiv mentioned a few examples, we have one of **the most diverse and strongest pipeline in biosimilars to follow that. So what that means is in the future, that portfolio, that pipeline will translate into a commercial portfolio and gives us one of the strongest commercial portfolios in the industry. I believe that having that broad portfolio is actually**

<p>November 8, 2021 Viatris Inc. Quarter 3, 2021 Earnings Call</p>	<p><b>important.</b></p> <p>So I agree with Rajiv. It's too early to declare winners and losers in the market. It's a developing market. <b>And you should fully expect us, again, as part of the strategic plan process that we'll look into the biosimilar opportunity very deeply, and then we consider it, and we'll make it a significant source of growth for Viatris going forward.</b></p> <p><b>Statement No. 54</b></p> <p>Before I get into the quarter at hand, I would like to echo Michael's excitement about our upcoming investor event. What you can expect to hear from me is a comprehensive review of the <b>significant value and the depth of our pipeline and clinical programs, including biosimilars</b>, complex generics and our medicines <b>that we have been strategically building over many years. These development programs are expected to play a significant role in our ability to drive organic growth over time</b>, especially as our cost synergies roll off at the end of 2023. Once laid out in January, <b>we believe our pipeline will be recognized as one of the company's most underappreciated assets</b> that will enable us to continue to deliver value while fulfilling our mission of expanding access and addressing patient needs.</p>
<p>December 1, 2021 Evercore ISI HealthCONx Conference</p>	<p><b>Statement No. 57</b></p> <p><u>Umer Raffat (Evercore ISI)</u></p> <p>I know from a business perspective, the Street expectations on your business are sort of in 2 phases right now. There is a near-term phase where business is being modeled to be flattish, and then there's a post '23 phase when some of the investments historically from the R&amp;D organization in the biosimilar starts to set the case for growth. Is that consistent with how you guys think about it? And how does that translate from an EBITDA perspective near term versus post '23?</p> <p><u>Michael Goettler</u></p> <p>We think of it also in 2 phases. We look at it in the Phase I where our commitments are very, very clear, and then a Phase II. We're not giving guidance today. Obviously, we're going to lay out on our Investor Day exactly how we deliver on our commitments for Phase I. <b>And then we're going to give you the catalyst for the</b></p>

	<p><b>growth in Phase II. And the catalysts are our pipeline, which we think is underappreciated. We’ve got some very strong investments in biosimilars, in complex generics that will drive it. We’re going to talk about our capital allocation priorities for that time and how we unlock value for shareholders. And I think the pipeline is really key.</b></p>
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Defendants argue that Viatris, through public disclosures, identified these product pipeline and portfolio statements as forward-looking, and that courts have routinely recognized them as such. Further, Defendants maintain that Viatris repeatedly and expressly warned shareholders from the outset of the Class Period that Viatris was evaluating, among other things, potential material divestitures of products and business on an ongoing basis and that such divestitures could reduce the size or scope of its businesses.

Plaintiffs contend that each of the above statements conveyed the misleading impression that Viatris remained committed and confident in its business model built on its broad and diversified portfolio of products, when, in fact, the Company was conducting the 2021 Strategic Review to transform that business model.

Here, as above, Defendants’ statements were forward-looking as “statements of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer.” 15 U.S.C. § 78u–5(i)(1)(B),(D). And again, courts routinely examine language, that is couched in future success, as forward-looking statements protected by the Safe Harbor statute. *See, e.g., Avaya*, 564 F.3d at 256-57 (statements that the company was “on track” and “position[ed]” to meet yearly goals were forward-looking); *In re Anadigics, Inc. Sec. Litig.*, 2011 WL 4594845, at \*21-23 (D.N.J. Sept. 30, 2011) (statement that “increased production capacity plans continue to progress” was forward-looking), *aff’d*, 484 F. App’x 742 (3d Cir. 2012). Likewise here, the statements include such forward-looking language such as

“we believe” (Statement No. 36), “will ensure a robust strategy” (Statement No. 49), “well-positioned to deliver” (Statement Nos. 24, 37), and “drive organic growth over time” (Statement No. 54). And as discussed above, such statements were coupled with clear disclosures regarding divestitures of products and business.

Accordingly, the Safe Harbor provisions apply to statements Nos. 4, 11, 13, 20, 24, 29, 34, 36, 37, 41, 47, 49, 50, 51, 54, and 57 as set forth in Plaintiffs’ Amended Complaint.

## 2. Corporate Optimism

Context	Statement Nos. 4, 5, 9, 11, 13, 15, 16, 18, 20, 23, 24, 25, 31, 34, 36, 37, 44, 46, 48, 49, 51, 54, 57, and 58
March 1, 2021 Viatris Inc. Analyst/Investor Day Call	<p><b>Statement No. 4</b></p> <p>Our goal over the last few years has been to move up the value chain from a science perspective. The complex generics and the biosimilars require, not only just high R&amp;D spend, I think it requires a high level of the science, more complex science, executing through that complex science, regulatory strategy, IP legal skill sets. And I believe we have already shown that we have those core competencies to excel in this space through some first-to-market successes like generic Advair, generic to the Advair, generic to the Copaxone, biosimilar to Neulasta, biosimilar to Herceptin, and I can go on.</p> <p>While we are very proud of our track record, we also believe that we can do a lot more in this space and better serve the patient needs by breaking down these barriers. <b>These investments have enabled us to see durable long-term revenue streams as compared to the core generics. And we see this as a core part of our forward-looking Viatris portfolio.</b></p> <p><b>Statement No. 5</b></p> <p>We take all of this forward and are committed to our next steps to leverage, not only in science, but our commercial capabilities to get the most out of this franchise. That commitment includes quickly ramping up the investments in our commercial capabilities wherever necessary, in certain markets, if there is opportunity to expand the access, drive uptake and help the market realize those cost savings. We also continue to remain committed to invest in the biosimilar development programs. And Walt will talk in a lot of detail about our biosimilar pipeline, where we are with the pipeline, with the development programs. But I would just like to highlight that we will be extremely focused on our efforts to be the first to the market and believe we are well positioned for several of our key programs in the future. Viatris is committed from</p>

<p>March 10, 2021 Barclays Global Healthcare Conference 2021</p>	<p>scientific as well as from the commercial capabilities and know how to be a long-term leader in this space.</p> <p><b>Statement No. 9</b></p> <p>[W]hat I would say, look, Viatris came into being a little bit more than 100 days ago, November 16, right? And as we got together, we said exactly what we said we're going to do, is we're going to get the 2 companies together, get immediately started on understanding the business, have the new manager understand each part of the business, build a bottom-up budget of quality, and then that's accumulated in February in our guidance. And as I said, we guided with a midpoint of 6.2 for EBITDA. That is our base, right? That's guidance that takes all the puts and takes into account that we see in the business and that we think is the right starting point for us as part of the interest.</p> <p>Now what you also have to appreciate, what this is, <b>all the strategic tenants that we've been talking about for 2 years now, almost, right, are in place.</b> This is a business that is <b>transformative and global scale</b>, right?</p> <p>The same for the <b>product portfolio. It's diverse. It's differentiated.</b> There's opportunities there. And on Investor Day, Rajiv gave a couple of good examples of how, going forward, we can leverage that.</p> <p><b>Statement No. 11</b></p> <p><u>Balaji V. Prasad (Barclays Bank PLC)</u></p> <p>[O]n the question of biosimilars. Can you help us understand how should -- how we need to think about competition in the space? There are not too many players globally who would want to be global biosimilar players, right, who are -- were in that capacity. And I can also see the advantage partners having partners from other economies or geographies (inaudible). And Sandoz just came out recently, an hour ago maybe, saying that they expect biosimilars to be a major growth engine for them globally. And what would competition entail for you? And is it going to be where you vastly talk on losing economics as it happened in the generic side? Or is this going to be much more impact to opportunity?</p> <p><u>Rajiv Malik</u></p> <p>I think we always said that <b>biosimilar for us is not a U.S.-specific business or a market-specific business. For us, it's a global franchise.</b> And we -- I gave in my Investor Day, I gave example of one Herceptin biosimilar being launched from one country and today being in 65 countries.</p>
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<p>May 10, 2021  Viatis Inc.  Quarter 1, 2021  Earnings Call</p>	<p>And you're so right, there is no global competition. Yes, Sandoz is now shaping up as a global sort of competitor, but many of these markets, especially the emerging markets, there are -- this is something which you can't play much locally. Now, of course, there is a competition coming in from some of the Indian biosimilar players, which we will have that, but I think we have the advantage that -- from our partners point of view, that we have the infrastructure to take it to the -- any part of the world, right from the China to the Latin America, to the Africa. So that's the advantage of partnering with somebody like us.</p> <p>And I'll tell you, our commercial infrastructure in these markets enables us to get more of this platform in -- just starting with what we have -- already what we have. <b>And we see that this will continue to be one of the key growth drivers as we launch more and more of these products in more geographies.</b></p> <p><b>Statement No. 13</b></p> <p>This quarter, we generated USD 163 million in new product revenue to partially offset inherent product erosion, and we're on track to achieve USD 690 million in new product revenue for the full year. <b>We're continuing to shift to more differentiated and sustainable portfolio with strong growth in complex generics and biosimilars and growth of our recently acquired thrombosis franchise in Europe.</b></p> <p><b>Statement No. 15</b></p> <p>Look, what we said is, again, we're not giving guidance at this point. <b>But the 6.2[] as a floor, we're highly, highly confident in because we know all the levers that we can have. We know the robustness of our business and our EBITDA you can put any leverage.</b> Free cash flow, high confidence again because <b>we clearly see the growth coming driven by EBITDA</b> and lower onetime costs. On revenue, we've got a good understanding of the base erosion that we have in the business. <b>We have a good understanding of the new pipeline revenue we can bring.</b> But if you look at it quarter-on-quarter or even year-on-year, it can be a bit choppy because of things like COVID, for example, or because of URP China timing. If that gets further delayed, that would change a little bit how '21 over '22 develops.</p> <p><b>Statement No. 16</b></p> <p>Let me just summarize. You've seen our first quarter results. They're very strong. We're very confident, proud of them, and they <b>validate the strength of the diversified and robust business model that we have and that differentiates us as a company.</b></p>
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<p>May 18, 2021 RBC Capital Markers Healthcare Conference</p>	<p><b>Statement No. 18</b></p> <p>Viatis as a combined company, is still a relatively new company, formed a little bit less than 6 months ago, in November. <b>And the vision we had was to create a new kind of health care company, one that's differentiated by a truly global operating platform, one that has scale.</b> It has commercial capabilities and has expertise in science, in manufacturing and legal and IP; secondly, <b>one that has a broad and diversified product portfolio. It's very important to us across brands, complex generics and biosimilars and generics and, very importantly, one that's agnostic to any particular therapeutic area, dosage form delivery mechanism, et cetera; and thirdly, one that has a strong R&amp;D platform that's well positioned to deliver a broad pipeline of complex and novel product, including our late-stage biosimilar pipeline.</b></p> <p>So just a few days ago, we were able to report the results of our first full quarter, and I'm happy to say it was a very strong and high quality quarter for us. And we believe that those results <b>validate the success of that diversified and robust business model that I just explained</b>, one that can absorb headwinds in any particular part of the world while seizing on opportunities when and where they present themselves. <b>And our results this quarter, we believe, reflect that.</b></p> <p><b>Statement No. 20</b></p> <p>Number one is <b>we know the robust business model that we have.</b> Now that's <b>balanced, that's diversified.</b> We can absorb the headwinds and tailwinds. So we have high confidence in that, and again, our first quarter results reflect that. We understand the <b>base business that we have and the natural erosion that we have in that base business. We understand what our pipeline can deliver.</b></p>
<p>June 10, 2021 Goldman Sachs Healthcare Conference</p>	<p><b>Statement No. 23</b></p> <p>On the portfolio side, we have <b>a broad and diverse product portfolio, that includes brands, that includes generics, that includes complex generics and biosimilars. That portfolio is synergistic, but it's agnostic to any particular therapeutic area, dosage form or delivery mechanisms, right? So that diversity gives us stability, allows us to balance any kind of negative impact in any particular part of the business, but jumping on opportunities as we see them.</b></p> <p><b>Statement No. 24</b></p> <p>A strong R&amp;D platform that is proven, well positioned to deliver <b>a broad pipeline of complex and novel products, including our late-stage</b></p>

<p>August 9, 2021  Viatis Inc.  Quarter 2, 2021  Earnings Call</p>	<p><b>biosimilars</b> and we have over 10 biosimilars in development in oncology, ophthalmology, immunology, diabetes and others.</p> <p><b>Statement No. 25</b></p> <p><b>So that's what we've built, right?</b> And then very recently, we published our first full quarter, quarter 1 results, and we saw really underlying strengths to our business. <b>And importantly, I think that strength of our results starts to validate that diversified robust business model that differentiates us as a company.</b></p> <p><b>Statement No. 31</b></p> <p>I'm pleased to say that the strong execution we showed in the first quarter has continued into the second quarter. ... Today's strong results...<b>validate the vision and the strategy we have in combining the 2 legacy organizations...</b></p> <p>Mylan brought Viatis portfolio diversity, a rich R&amp;D pipeline, strong internal scientific capabilities and proven integration expertise. And Upjohn provided strong iconic brands, a global commercial engine and scale in critical markets. The result is an even stronger future-ready and resilient platform with enhanced global scale and geographic reach, <b>a sustainable, diverse and differentiated portfolio and pipeline</b>, a powerful operating platform and strong commercial capabilities with significant future potential and the power to generate strong and sustainable cash flows.</p> <p><b>Statement No. 34</b></p> <p>Lastly, and as I've already mentioned, I cannot emphasize enough the impressive R&amp;D engine and scientific capabilities that we have. <b>As we prepare to deliver our strategic plan, you can fully expect that we will continue to add high-value assets to our pipeline and further leverage our scientific expertise and R&amp;D platform.</b></p> <p><b>Statement No. 36</b></p> <p>Our global generics business grew by 8% year-over-year and performed better than our expectations. We delivered \$224 million for new launches in the second quarter. And as we look ahead, we remain on track to meet our \$690 million target in 2021. <b>We believe that the diversity of our portfolio and commercial reach positions us well to balance the impact of any changes in the market and eliminate our reliance on any one product or geography. Accordingly, we expect our base business to continue to perform strongly.</b></p>
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<p>September 10, 2021 Citi Biopharma Conference</p>	<p><b>Statement No. 37</b></p> <p>Our Developed Markets segment grew by 2% year-over-year. . . . <b>Our biosimilars performed strongly with 47% growth this quarter, which helped offset the negative impact of the previously anticipated competition to Wixela and XULANE.</b> Our generics portfolio also performed better than our expectations, primarily driven by our U.S. injectables portfolio, as well as favorable COVID-related buying patterns in Europe. Having said that, <b>we see our biosimilars portfolio driving continued growth while offsetting anticipated competition in our complex generics space.</b></p> <p>. . .</p> <p>It can take, on average, 7 to 9 years from development to regulatory approval, given the highly complex nature of these molecules. Getting to the finish line requires tremendous perseverance, tenacity and an unwavering commitment to patients. The success stories of receiving the first approval for our Copaxone 40-milligram, Advair, Neulasta, Herceptin, Symbicort, and <b>most recently, the first interchangeable biosimilar to the Lantus, give us great confidence that we are well positioned to deliver on our pipeline.</b> We intend to leverage our deep scientific capabilities to further expand access to the complex products for patients.</p> <p><b>Statement No. 44</b></p> <p><u>Navann Ty (Citi)</u></p> <p>Switching to business development. What is – maybe staying on the credit profile. What is the gross leverage -- is there a gross leverage level that Viatrix should reach before considering business development?</p> <p><u>Michael Goettler</u></p> <p>. . . And I think investors should not forget, in addition to BD, we – or actually BD is the addition to the R&amp;D engine that we have. We have a strong internal R&amp;D engine. So we actually – especially in biosimilars, complex generics. <b>So we're actually in a position to be very disciplined. We're in a position to be very choosy and only add the right deals when we see them.</b> But don't mistake our commitments for lack of activity and interest [in this business area].</p> <p><b>Statement No. 46</b></p> <p>There are many not just one, there are many exciting opportunities in our pipeline. <b>For the last several years, we have been working diligently to</b></p>
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**move our pipeline towards more complex and biosimilars.** And we have several notable successes over these last few years. **Today as an outcome of this, we have a robust pipeline with 75% of our pipeline spent in that bucket.** There we are basically focusing on the complexity.

**Statement No. 48**

**Biosimilar[s] is and will continue to be an important area for the company and will be a key growth driver, a key driver for our future growth.** And let me also say, it's a little bit too early in the biosimilar space as this market is evolving, as it's in its infancy that we should say that we should not go on the predicting game of the winners and losers.

**Statement No. 49**

**The first part of our strategy is to build the portfolio because we believe having a deep and broad offering around commercial portfolio will ensure a robust strategy, will be the first leg of delivering the strategy.** And I just gave you several examples of our pipeline where we are either executed already or well on our way to execute on that.

**Statement No. 51**

Yes. I think, Rajiv, you hit on the key points. And maybe what I can add is from a strategy perspective, it's very clear that biosimilars is not a mature market yet, and it's a growing market. **There's no doubt about it. And therefore, with the capabilities we have, it is and will be and can be a growth driver for Viatis.**

We've made significant investments in building the pipeline. We've shown that we can deliver on the science and bring these innovative products to the market. We have only a few molecules now, but already these few molecules are 150 marketing authorizations in 85 countries. So it shows our ability to take this and really take a global approach to it.

And we have, and Rajiv mentioned a few examples, we have one of **the most diverse and strongest pipeline in biosimilars to follow that. So what that means is in the future, that portfolio, that pipeline will translate into a commercial portfolio and gives us one of the strongest commercial portfolios in the industry. I believe that having that broad portfolio is actually important.**

So I agree with Rajiv. It's too early to declare winners and losers in the market. It's a developing market. **And you should fully expect us, again, as part of the strategic plan process that we'll look into the biosimilar opportunity very deeply, and then we consider it, and we'll make it a**

<p>November 8, 2021  Viatis Inc.  Quarter 3, 2021  Earnings Call</p>	<p><b>significant source of growth for Viatis going forward.</b></p> <p><b>Statement No. 54</b></p> <p>Before I get into the quarter at hand, I would like to echo Michael's excitement about our upcoming investor event. What you can expect to hear from me is a comprehensive review of the <b>significant value and the depth of our pipeline and clinical programs, including biosimilars</b>, complex generics and our medicines <b>that we have been strategically building over many years. These development programs are expected to play a significant role in our ability to drive organic growth over time</b>, especially as our cost synergies roll off at the end of 2023. Once laid out in January, <b>we believe our pipeline will be recognized as one of the company's most underappreciated assets</b> that will enable us to continue to deliver value while fulfilling our mission of expanding access and addressing patient needs.</p>
<p>December 1, 2021  Evercore ISI  HealthCONx  Conference</p>	<p><b>Statement No. 57</b></p> <p><u>Umer Raffat (Evercore ISI)</u></p> <p>I know from a business perspective, the Street expectations on your business are sort of in 2 phases right now. There is a near-term phase where business is being modeled to be flattish, and then there's a post '23 phase when some of the investments historically from the R&amp;D organization in the biosimilar starts to set the case for growth. Is that consistent with how you guys think about it? And how does that translate from an EBITDA perspective near term versus post '23?</p> <p><u>Michael Goettler</u></p> <p>We think of it also in 2 phases. We look at it in the Phase I where our commitments are very, very clear, and then a Phase II. We're not giving guidance today. Obviously, we're going to lay out on our Investor Day exactly how we deliver on our commitments for Phase I. <b>And then we're going to give you the catalyst for the growth in Phase II. And the catalysts are our pipeline, which we think is underappreciated. We've got some very strong investments in biosimilars, in complex generics that will drive it.</b> We're going to talk about our capital allocation priorities for that time and how we unlock value for shareholders. <b>And I think the pipeline is really key.</b></p> <p><b>Statement No. 58</b></p> <p>So those launches, I think, the <b>concentration of those complex launches starts building up.</b> And also, you would see the contribution of '22, '23</p>

	launches is not going to fade out. <b>So I'm very excited to share with you guys on the Investor Day what are the catalysts for Phase 2 and how they're going to contribute to the -- and it's going to -- my feel is, once we do all that math, it's is going to make our base business relatively more durable than it was yesterday or it [was] today.</b>
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Next, Defendants argue that the above statements are vague statements of corporate optimism that are understood as puffery to reasonable investors. Defendants maintain that such statements are immaterial and thus, not actionable as a matter of law.

Plaintiffs contend that none of Defendants' statements and omissions could be found to be "obviously unimportant" to investors so as to be immaterial.

The Third Circuit has routinely affirmed dismissal of securities fraud claims based upon statements that are inactionable puffery. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 284 (3d Cir. 2010); *see also, e.g., City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 172 (3d Cir. 2014); *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999). The Third Circuit and its district courts has also regularly dismissed securities fraud claims based on similar corporate self-praise, finding that superlatives ranging from "among the best in the industry" to "excellent" or "high quality" are nonactionable puffery. *Advanta*, 180 F.3d at 537-38; *see also Galati v. Commerce Bancorp, Inc.*, 220 F. App'x 97, 101-02 (3d Cir. 2007) (statements concerning the company's "dramatic deposit growth," "strong performance," and "unique business model" constitute nothing more than "mere 'puffery'") (quoting *Advanta*, 180 F.3d at 538-39); *Martin*, 2017 WL 3974002, at \*8 (rejecting as puffery statements touting GNC as an "industry leader" who "sets the industry standard"); *Fusco v. Uber Techs., Inc.*, 2018 WL 3618232, at \*7 (E.D. Pa. July 27, 2018) ("robust" is puffery; it is an "exaggeration or overstatement expressed in broad, vague, and commendatory language") (citation omitted). *See, e.g., In re Hertz Global Holdings, Inc. Sec. Litig.*, 2017 WL 1536223, at \*10-11 (D.N.J. Apr. 27, 2017) (challenged statements

about “strong” and “record” financial results, and optimistic statements about financial growth such as “we feel very confident the story is intact” are nonactionable puffery), *aff’d*, 905 F.3d 106 (3d Cir. 2018); *City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1064 (N.D. Cal. 2012) (“growth drivers give us confidence” is “simply [a] vague assertion[] of corporate optimism” and not actionable). *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 284 (3d Cir. 2010) (general descriptors such as “disciplined” and expressing commitment to “discipline and rigor” were puffery); *Key Equity Inv’rs, Inc. v. Sel-Leb Mktg. Inc.*, 246 F. App’x 780, 785 (3d Cir. 2007) (“positive portrayals of the company” including “expressions of general optimism about [company’s] financial health” are puffery).

Here, the language in the above statements is rife with non-actionable words of corporate optimism and puffery. For example, Defendants describe Viatris’ business model and its pipeline as “robust” (Statement Nos. 15, 16, 18, 20, 25, 46, 49), its product portfolio as “broad,” “diverse,” “diversified,” and “differentiated” (Statement Nos. 9, 13, 16, 18, 20, 23, 24, 31, 36), and its pipeline and portfolio as “one of the most diverse and strongest . . . in the industry” (Statement No. 51) and as adding “significant value and . . . depth” (Statement No. 54). In addition, Defendants’ statements include descriptions such as, its “very strong investments in biosimilars, in complex generics” (Statement No. 57), its “strong growth in complex generics and biosimilars” (Statement No. 13), its “great confidence that we are well positioned to deliver on our pipeline” (Statement No. 37), its expectation that “our base business [will] continue to perform strongly” (Statement No. 36), and that biosimilars “will continue” to be a “key growth driver” (Statement Nos. 11, 48). Finally, Viatris’ statements tout that it is a “long-term leader in this space” (Statement No. 5), that its long-term revenue streams were “durable” (Statement No. 4), that its “base business [is] relatively more durable” (Statement No. 58), that it would continue

to add “high-value assets” to the pipeline (Statement No. 34), and that it was “in a position to be very disciplined” and “very choosy” (Statement No. 44) with respect to transactions. All of these statements contain quintessential puffery statements of corporate optimism that courts have routinely dismissed as failing to support a securities fraud claim, because they contain immaterial information that would be unimportant to an investor. And even if said statements were not puffery or statements of optimism, they are intertwined with the forward-looking statements that the Court has found above to be protected under the Safe Harbor provisions.

Accordingly, the statements of puffery and corporate optimism within Statement Nos. 4, 5, 9, 11, 13, 15, 16, 18, 20, 23, 24, 25, 31, 34, 36, 37, 44, 46, 48, 49, 51, 54, 57, and 58 do not support a securities fraud claim in Plaintiffs’ Amended Complaint.

### 3. Opinion Statements

Context	Statement Nos. 4, 5, 36, 49, 51, 54, and 57
March 1, 2021 Viatris Inc. Analyst/Investor Day Call	<p data-bbox="451 1035 673 1073"><b>Statement No. 4</b></p> <p data-bbox="451 1108 1443 1402">Our goal over the last few years has been to move up the value chain from a science perspective. The complex generics and the biosimilars require, not only just high R&amp;D spend, I think it requires a high level of the science, more complex science, executing through that complex science, regulatory strategy, IP legal skill sets. And I believe we have already shown that we have those core competencies to excel in this space through some first-to-market successes like generic Advair, generic to the Advair, generic to the Copaxone, biosimilar to Neulasta, biosimilar to Herceptin, and I can go on.</p> <p data-bbox="451 1438 1443 1623">While we are very proud of our track record, we also believe that we can do a lot more in this space and better serve the patient needs by breaking down these barriers. <b>These investments have enabled us to see durable long-term revenue streams as compared to the core generics. And we see this as a core part of our forward-looking Viatris portfolio.</b></p> <p data-bbox="451 1659 673 1696"><b>Statement No. 5</b></p> <p data-bbox="451 1732 1443 1877">We also <b>continue to remain committed to invest in the biosimilar development programs.</b> And Walt will talk in a lot of detail about our biosimilar pipeline, where we are with the pipeline, with the development programs. But I would just like to highlight that we will be <b>extremely</b></p>



<p>August 9, 2021 Viartis Inc. Quarter 2, 2021 Earnings Call</p> <p>September 10, 2021 Citi Biopharma Conference</p>	<p><b>focused on our efforts to be the first to the market and believe we are well positioned for several of our key programs in the future.</b></p> <p><b>Statement No. 36</b></p> <p>Our global generics business grew by 8% year-over-year and performed better than our expectations. We delivered \$224 million for new launches in the second quarter. And as we look ahead, we remain on track to meet our \$690 million target in 2021. <b>We believe that the diversity of our portfolio and commercial reach positions us well to balance the impact of any changes in the market and eliminate our reliance on any one product or geography. Accordingly, we expect our base business to continue to perform strongly.</b></p> <p><b>Statement No. 49</b></p> <p><b>The first part of our strategy is to build the portfolio because we believe having a deep and broad offering around commercial portfolio will ensure a robust strategy,</b> will be the first leg of delivering the strategy. And I just gave you several examples of our pipeline where we are either executed already or well on our way to execute on that.</p> <p><b>Statement No. 51</b></p> <p>Yes. I think, Rajiv, you hit on the key points. And maybe what I can add is from a strategy perspective, it's very clear that biosimilars is not a mature market yet, and it's a growing market. <b>There's no doubt about it. And therefore, with the capabilities we have, it is and will be and can be a growth driver for Viartis.</b></p> <p>We've made significant investments in building the pipeline. We've shown that we can deliver on the science and bring these innovative products to the market. We have only a few molecules now, but already these few molecules are 150 marketing authorizations in 85 countries. So it shows our ability to take this and really take a global approach to it.</p> <p>And we have, and Rajiv mentioned a few examples, we have one of <b>the most diverse and strongest pipeline in biosimilars to follow that. So what that means is in the future, that portfolio, that pipeline will translate into a commercial portfolio and gives us one of the strongest commercial portfolios in the industry. I believe that having that broad portfolio is actually important.</b></p> <p>So I agree with Rajiv. It's too early to declare winners and losers in the market. It's a developing market. <b>And you should fully expect us, again,</b></p>
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<p>November 8, 2021  Viatis Inc.  Quarter 3, 2021  Earnings Call</p>	<p><b>as part of the strategic plan process that we'll look into the biosimilar opportunity very deeply, and then we consider it, and we'll make it a significant source of growth for Viatis going forward.</b></p> <p><b>Statement No. 54</b></p> <p>Before I get into the quarter at hand, I would like to echo Michael's excitement about our upcoming investor event. What you can expect to hear from me is a comprehensive review of the <b>significant value and the depth of our pipeline and clinical programs, including biosimilars, complex generics and our medicines that we have been strategically building over many years. These development programs are expected to play a significant role in our ability to drive organic growth over time,</b> especially as our cost synergies roll off at the end of 2023. Once laid out in January, <b>we believe our pipeline will be recognized as one of the company's most underappreciated assets</b> that will enable us to continue to deliver value while fulfilling our mission of expanding access and addressing patient needs.</p>
<p>December 1, 2021  Evercore ISI  HealthCONx  Conference</p>	<p><b>Statement No. 57</b></p> <p><u>Umer Raffat (Evercore ISI)</u></p> <p>I know from a business perspective, the Street expectations on your business are sort of in 2 phases right now. There is a near-term phase where business is being modeled to be flattish, and then there's a post '23 phase when some of the investments historically from the R&amp;D organization in the biosimilar starts to set the case for growth. Is that consistent with how you guys think about it? And how does that translate from an EBITDA perspective near term versus post '23?</p> <p><u>Michael Goettler</u></p> <p>We think of it also in 2 phases. We look at it in the Phase I where our commitments are very, very clear, and then a Phase II. We're not giving guidance today. Obviously, we're going to lay out on our Investor Day exactly how we deliver on our commitments for Phase I. <b>And then we're going to give you the catalyst for the growth in Phase II. And the catalysts are our pipeline, which we think is underappreciated. We've got some very strong investments in biosimilars, in complex generics that will drive it.</b> We're going to talk about our capital allocation priorities for that time and how we unlock value for shareholders. <b>And I think the pipeline is really key.</b></p>

Defendants next argue that challenged statement numbers 4, 5, 36, 49, 51, 54, and 57 contain or are otherwise nonactionable statements of opinion. Plaintiffs contend these statements assert fact, not opinion, about Viatris' commitment to its biosimilars growth strategy. In response, Defendants maintain that Plaintiffs' arguments are based upon editing out key portions of the challenged statements.

“Statements that ‘express expectations about the future rather than presently existing, objective facts’ are statements of opinion.” *In re Supercom Inc. Sec. Litig.*, 2018 WL 4926442, at \*22 (S.D.N.Y. Oct. 10, 2018) (citation omitted). Such statements are often marked by phrases such as “I believe” and “I think,” *see Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 183-84 (2015), and are nonactionable unless they are “(1) not honestly believed and (2) lack a reasonable basis.” *Amarin*, 689 F. App'x at 132 (citing *Pfizer*, 754 F.3d at 170). They remain inactionable regardless of whether the belief is later proven to be wrong. *Tanaskovic v. Realogy Holdings Corp.*, 2021 WL 211049, at \*19-20 (D.N.J. Jan. 21, 2021) (citing *Omnicare*, 575 U.S. at 182-88).

Here, the challenged statements reflect Defendants' opinions regarding the future of the Company's product portfolio and pipeline. *See e.g.*, Statement No. 36 (“We believe that the diversity of our portfolio and commercial reach positions us well to balance the impact of any changes in the market[.]”); Statement No. 49 (“[W]e believe having a deep and broad offering around commercial portfolio will ensure a robust strategy[.]”); Statement No. 54 (“[W]e believe our pipeline will be recognized as one of the company's most underappreciated assets.”); *see also* Statement Nos. 4, 5, 51, and 57. Such language falls squarely within the realm of nonactionable language because they express future expectations and not present facts. Otherwise, the Amended Complaint alleges no facts indicating that the Defendants' opinions

were “not honestly believed” or that they “lacked a reasonable basis” at the time when they were made. And again, as discussed in depth above, the Amended Complaint contains no allegation that plausibly confirms a misleading statement when Defendants had already disclosed its consideration of divestitures.

Accordingly, the statements of opinion within Statement Nos. 4, 5, 36, 49, 51, 54, and 57 do not support a securities fraud claim in Plaintiffs’ Amended Complaint.

#### 4. Other Statements

Context	Statement Nos. 18, 22, 23, 26, 27, 32, 37, 45, 46, 55, 56
May 18, 2021 RBC Capital Markers Healthcare Conference	<p><b>Statement No. 18</b></p> <p>Viartis as a combined company, is still a relatively new company, formed a little bit less than 6 months ago, in November. <b>And the vision we had was to create a new kind of health care company, one that's differentiated by a truly global operating platform, one that has scale.</b> It has commercial capabilities and has expertise in science, in manufacturing and legal and IP; secondly, <b>one that has a broad and diversified product portfolio. It's very important to us across brands, complex generics and biosimilars and generics and, very importantly, one that's agnostic to any particular therapeutic area, dosage form delivery mechanism, et cetera; and thirdly, one that has a strong R&amp;D platform that's well positioned to deliver a broad pipeline of complex and novel product, including our late-stage biosimilar pipeline.</b></p> <p>So just a few days ago, we were able to report the results of our first full quarter, and I'm happy to say it was a very strong and high quality quarter for us. And we believe that those results <b>validate the success of that diversified and robust business model that I just explained</b>, one that can absorb headwinds in any particular part of the world while seizing on opportunities when and where they present themselves. <b>And our results this quarter, we believe, reflect that.</b></p> <p><b>Statement No. 22</b></p> <p>For longer-term targets, and to give you some color on that, we need to do the internal. <b>Our business model is very different from, let's say, brand pharma, where you have relatively limited portfolio that you focus on and gets centrally driven and then you're kind of looking for the country where you can sell it. Our model is very different.</b> We have 1,400 molecules, and we tailor that portfolio to the individual market. We tailor our R&amp;D to the demand</p>

<p>June 10, 2021 Goldman Sachs Healthcare Conference</p>	<p>and what we think is right for the market. <b>So it requires a bottom-up work. That bottom-up work takes time. And we just started that strat plan, what we call strat plan process, and we'll get back to you towards the end of the year with a bit more color on that.</b></p> <p><b>Statement No. 23</b></p> <p>On the portfolio side, we have <b>a broad and diverse product portfolio, that includes brands, that includes generics, that includes complex generics and biosimilars. That portfolio is synergistic, but it's agnostic to any particular therapeutic area, dosage form or delivery mechanisms, right? So that diversity gives us stability, allows us to balance any kind of negative impact in any particular part of the business, but jumping on opportunities as we see them.</b></p> <p><b>Statement No. 26</b></p> <p>Nathan Allen Rich (Goldman Sachs Group, Inc.)</p> <p>But with the base business erosion, can you maybe talk about the components of that? Why you feel comfortable that 3% to 4% is the right number? And how that maybe breaks down across the different businesses that you have when we think about brands, generics and complex products and biosimilars?</p> <p><u>Sanjeev Narula</u></p> <p>I think you need to understand and appreciate what is driving that. And one is this, the resilience. 60% of this is brands, 30% is generics and 10% is complex and biosimilars today. <b>And it's moving more towards the complex and biosimilars. . .</b></p> <p>. . . .</p> <p><b>Now pocket of biosimilars is growing. As you saw, Q1 was 27% growth in that bucket of complex and biosimilars. That's very much all the biosimilar growth, 27% worth of biosimilars growth.</b></p> <p><b>Statement No. 27</b></p> <p><u>Nathan Allen Rich (Goldman Sachs Group, Inc.)</u></p> <p>Could you maybe help us think about across the different areas, biosimilars, complex products, injectables, sort of the relative sizes of the opportunities and maybe what you're most excited about in terms of coming to market over the next several years?</p>
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<p>August 9, 2021 Viatris Inc. Quarter 2, 2021 Earnings Call</p>	<p><u>Rajiv Malik</u></p> <p>A lot of opportunities in this pipeline. <b>And over a period of time, it is moving from value chain perspective. Today, almost 75% of our portfolio is around complex and biosimilars.</b> We are not moving away from generics, but we have been smart about that. We have been diligent about that, that how we pick our spots and compete in that.</p> <p>So when it comes to the biosimilars, I think next couple of years, will be an opportunity like -- and I'm excited by EYLEA. I think we are still -- because as you've seen by this time, not in U.S.A., everywhere else also, <b>the first to market is becoming a decisive advantage. And that's where our -- we want to focus on, how can we be the first to the market.</b> And EYLEA is -- we just had a successful readout of our Phase III. We are in very much as we have said that we'll be filing this we are able -- within this year. We remain on track. That's one.</p> <p>BOTOX is very exciting for us because, <b>again, we are leading the pack over here,</b> having good engagement with the FDA. FDA is excited that there are some restocking about bringing another biosimilar over here. So I think that's building up.</p> <p><b>Statement No. 32</b></p> <p>But performance extends not only to our commercial segments but also to our operations.... <b>In July, we received a historic approval from the U.S. Food and Drug Administration for the industry's first-ever interchangeable biosimilar product in the U.S., Semglee or insulin glargine.</b> We're extremely proud of this achievement, which will help broaden access to this important diabetes medicine for patients, for physicians, for payers and for providers.</p> <p>And as you know from what's said by FDA and policymakers throughout the government, there is significant interest in this approval and what it can mean for patients and the health care system overall, both now and in the future. The interchangeable assembly product, which will allow for substitution for the reference product at the pharmacy counter, will be introduced before the end of the year.</p> <p>Assembly is not the only advancement in our pipeline this quarter. With regard to our biosimilar and complex products pipeline, we're making steady progress across multiple programs, <b>which Rajiv will discuss in more detail. Overall, we generated \$224 million in new product revenue, and we continue to be on track for \$690 million in new product revenue for the full year.</b></p>
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<p>September 10, 2021 Citi Biopharma Conference</p>	<p><b>Statement No. 37</b></p> <p>Our Developed Markets segment grew by 2% year-over-year. . . . <b>Our biosimilars performed strongly with 47% growth this quarter, which helped offset the negative impact of the previously anticipated competition to Wixela and XULANE.</b> Our generics portfolio also performed better than our expectations, primarily driven by our U.S. injectables portfolio, as well as favorable COVID-related buying patterns in Europe. Having said that, <b>we see our biosimilars portfolio driving continued growth while offsetting anticipated competition in our complex generics space.</b></p> <p>. . .</p> <p>It can take, on average, 7 to 9 years from development to regulatory approval, given the highly complex nature of these molecules. Getting to the finish line requires tremendous perseverance, tenacity and an unwavering commitment to patients. The success stories of receiving the first approval for our Copaxone 40-milligram, Advair, Neulasta, Herceptin, Symbicort, and <b>most recently, the first interchangeable biosimilar to the Lantus, give us great confidence that we are well positioned to deliver on our pipeline.</b> We intend to leverage our deep scientific capabilities to further expand access to the complex products for patients.</p> <p><b>Statement No. 45</b></p> <p><u>Navann Ty (Citi)</u></p> <p>And what areas of indications would you consider for potential M&amp;A? And I think the last time we discussed, tuck-in acquisition Phase II assets, still the priority.</p> <p><u>Michael Goettler</u></p> <p>I think I'll give more clarity on that when we lay out a strategic plan. <b>Obviously, we're a company that's not focused on a particular therapeutic area at the moment.</b> We have broad opportunities, both geographic as well as therapeutic area wise. And as we layout the strategy, we can also then get more clarity on areas of focus going forward.</p> <p><b>Statement No. 46</b></p> <p>There are many not just one, there are many exciting opportunities in our pipeline. <b>For the last several years, we have been working diligently to move our pipeline towards more complex and biosimilars.</b> And we have several notable successes over these last few years. <b>Today as an outcome of this, we have a robust pipeline with 75% of our pipeline spent in that</b></p>
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<p>November 8, 2021  Viatis Inc.  Quarter 3,  2021 Earnings  Call</p>	<p><b>bucket. There we are basically focusing on the complexity.</b></p> <p><b>Statement No. 55</b></p> <p>Overall, the business performed strongly across all of our segments versus our expectations. . . . Our complex generics and biosimilar category performed in line with our expectations. <b>We are pleased with the continued growth of our global biosimilars portfolio this quarter, which grew by 14% and helped to offset anticipated competition related to select complex generics products.</b></p>
<p>December 1, 2021  Evercore ISI  HealthCONx  Conference</p>	<p><b>Statement No. 56</b></p> <p><u>Umer Raffat (Evercore ISI)</u></p> <p>And there was an interview last night with Novartis Chairman, where they were asked if there's any possibility of a combination with one of the large players like a Teva or Mylan, Viatis. I guess, how do you guys think about something like that? Is that even something you guys are even contemplating? Plus, wouldn't there be some massive antitrust problems with anything like that in the first place?</p> <p><u>Michael Goettler</u></p> <p>So all I can say is we also read the reports this morning of what Joerg Reinhardt commented. <b>I can tell you we haven't had any discussions on the topic.</b> Of course, if there's a possibility to create more shareholder value, we consider it, <b>but it's not something we're actively considering at this point.</b></p>

Defendants contend that these remaining statements are not actionable because they contain accurate statements concerning Viatis' financial results, product approvals, and product portfolio. Defendants further maintain that Plaintiffs have not attacked their accuracy or explain why they are misleading.

In their responses, Plaintiffs have not challenged the accuracy of Statement Nos. 22 and 55. As to the remaining, Plaintiffs rehashes its arguments that the statements are actionable because Viatis omitted from its statements that it was conducting a strategic review that included decisions whether the biosimilar business was "core" or "noncore."



Such accurate statements of historical results are not actionable. *Advanta*, 180 F.3d at 538 (“Factual recitations of past earnings, so long as they are accurate, do not create liability under Section 10(b).”); *Zucker v. Quasha*, 891 F. Supp. 1010, 1015 (D.N.J. 1995) (factually accurate statements of operating results not actionable), *aff’d mem.*, 82 F.3d 408 (3d Cir. 1996); *In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 400, 403-04 (S.D.N.Y. 2016) (accurate statements of past earnings and percentage growth in diabetes product sales not actionable).

Here, to the extent the above statements contain historical results, the same are not actionable. To the extent the statements potentially convey information regarding biosimilars, the same analysis from above applies here. At most, Plaintiff alleges that Viatrix, eventually, following the strategic review, changed its biosimilars strategy. And, as thoroughly discussed above, nothing in the Amended Complaint sufficiently pleads a securities fraud claim.

Accordingly, Statement Nos. 18, 22, 23, 26, 27, 32, 37, 45, 46, 55, and 56 in Plaintiffs’ Amended Complaint do not support a securities fraud claim.

#### IV. Conclusion

Following consideration of the foregoing, the challenged statements, which serve as an alleged basis for Plaintiffs’ Section 10(b) Securities Fraud claim, are not actionable under the Safe Harbor Provisions or otherwise lack the legal sufficiency to support the same. Therefore, Defendants’ Motion to Dismiss, as regards Section 10(b) (Count I), will be granted. Further, because Plaintiffs’ Section 20(a) Securities Fraud claim is derivative of their Section 10(b) claim, the Section 20(a) claim also lacks legal sufficiency. Thus, Defendants’ Motion to Dismiss, as regards Section 20(a) (Count II), will be granted.

Because the Amended Complaint and supporting documents provide sufficient context for this Court's analysis of Plaintiffs' allegations, any amendment will be deemed futile. A separate order will follow.

DATED this 20<sup>th</sup> day of September, 2024.

BY THE COURT:

  
MARILYN J. HORAN  
United States District Judge